14-4353-cv

United States Court of Appeals

for the

Second Circuit

APOTEX INC., APOTEX CORP.,

Plaintiffs-Appellants,

– v. –

ACORDA THERAPEUTICS, INC.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF AND SPECIAL APPENDIX
FOR PLAINTIFFS-APPELLANTS

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CORPORATE DISCLOSURE STATEMENT

Apotex Inc.'s parent corporation is Apotex Pharmaceutical Holdings, Inc. No publicly held corporation owns 10% or more of Apotex Inc.

Apotex Corp.'s parent corporation is Aposherm, Inc. No publicly held corporation owns 10% or more of Apotex Corp.

Respectfully submitted,

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes & Other Authorities:

INTRODUCTION

This case is about a product-hopping scheme that Acorda implemented to breathe new life into its fading drug franchise—Zanaflex—by persuading physicians to switch their patients from tablets to more expensive, monopoly-priced capsules. This scheme entailed (a) falsely advertising that Zanaflex Capsules reduce the well-known side effect of somnolence as compared to Zanaflex (and generic) tablets and then (b) forestalling generic competition in the capsule market.

Acorda knew that Zanaflex Capsules and Zanaflex (and generic) tablets had the same active ingredient (tizanidine) and treated the same condition (spasticity). And Acorda had tests comparing Zanaflex tablets and Zanaflex Capsules that failed to prove that the capsules offered any benefits over the tablets with respect to somnolence or otherwise. Nevertheless, Acorda created a promotional campaign that falsely hailed Zanaflex Capsules as more flexible than tablets because they provide the benefit of reduced somnolence and so can more readily be taken during the day.

Acorda's product-hopping scheme worked, but would be for naught if Acorda couldn't continue to charge monopoly prices for the capsules. That meant that Acorda also needed to block competition. Once again, Acorda overreached. The very day the district court entered judgment against Acorda in a patent-

infringement suit it had filed against Apotex, the first potential competitor in the capsule market, Acorda filed a sham petition with FDA that delayed approval of Apotex's generic capsules thereby illegally prolonging Acorda's monopoly. The same day FDA rejected Acorda's petition, it approved Apotex's generic product.

Acorda's scheme violated the antitrust laws and the Lanham Act, but the district court gave Acorda a pass on both transgressions.

In granting Acorda's motion to dismiss Apotex's antitrust claim, the district court failed to accept as true Apotex's allegations that Acorda's sham petition delayed approval of Apotex's tizanidine capsules. Instead, the court drew an impermissible inference against Apotex that a 2007 statute immunized brand drug companies from liability for filing sham petitions to delay generic competition. The court then compounded this error by holding that Apotex failed to make—at the dismissal stage—an "evidentiary proffer" that overcame the court's inference.

In granting summary judgment for Acorda on Apotex's Lanham Act claim, the court failed to heed this Court's requirement to assess Acorda's advertising as a whole to ascertain the overall promotional message. The court instead dissected each component of Acorda's promotional message with a fine scalpel—sometimes down to the sentence—and separately analyzed each discrete part independent of context. By proceeding myopically in that manner, the court lost sight of Acorda's overall message—the literally false claim that Zanaflex Capsules offer the benefit

of lower somnolence. And while the court concluded that a jury could find some of Acorda's advertising to be literally false, it ignored binding precedent when it required evidence that a literally false message influenced purchasing decisions. Then, the court overlooked record evidence that Acorda's false advertising *did in fact* influence purchasing decisions.

JURISDICTIONAL STATEMENT

This action involves violations of section 2 of the Sherman Act, 15 U.S.C. § 2, and section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). The district court had subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15 and 1121(a).

This appeal is from a final judgment entered on October 24, 2014 (SPA19), so this Court's jurisdiction rests on 28 U.S.C. § 1291. *See also* 15 U.S.C. § 1121(a). Apotex timely filed its notice of appeal within thirty days, on November 20, 2014. A4081-82; FED. R. APP. P. 4(a)(1).

STATEMENT OF THE ISSUES

1. Did Apotex's amended complaint state a plausible antitrust injury when it alleged that Acorda's sham citizen petition delayed FDA approval of Apotex's generic drug thereby delaying competition in the tizanidine-capsule market? Or did Apotex have to make an "evidentiary proffer" that the petition delayed approval, as the district court held?

2. Did the district court err when it denied Apotex leave to filed a second amended complaint (the first curative amendment) before Apotex could even file a motion for leave to amend? Was it error for the district court to base that denial on its assessment of the credibility of Apotex's proposed new allegations?

3. Did the district court err in granting summary judgment for Acorda where the record abounds with evidence establishing the literal falsity of Acorda's promotional message that Zanaflex Capsules offer the benefit of reduced somnolence? Did the court further err in demanding proof that literally false advertising would affect consumers' purchasing decisions and then in overlooking record evidence that it did affect those decisions?

STATEMENT OF THE CASE

Apotex, a generic-drug manufacturer, sued Acorda alleging that Acorda (1) violated the antitrust laws by filing a sham citizen petition with FDA that delayed competition in the tizanidine-capsule market, and (2) violated the Lanham Act by falsely advertising that Zanaflex Capsules were superior to Zanaflex and generic tizanidine tablets in an effort to convert consumers to the monopoly-priced capsules. A15-25.

Apotex filed its complaint in December 2011 while FDA was still considering Acorda's citizen petition, which Acorda had filed the day it lost an earlier patent suit against Apotex. A29; *see also* A20. In January 2012, Acorda

moved to dismiss under Rule 12(b)(6). A69-70. On February 3, 2012 FDA denied Acorda's citizen petition as "without merit". A414-21. Simultaneous with that denial, FDA approved Apotex's abbreviated new drug application (ANDA) to sell generic tizanidine capsules. A277 at ¶44, 415. The following day, Apotex launched its competing product. A277 at ¶45.

On February 21, 2012 Apotex filed an amended complaint solely to add these new developments. A270-87; *see also* A268-69. Acorda then withdrew its original motion to dismiss and filed a motion to dismiss the amended complaint. A288-89. So the operative complaint in this appeal is the amended complaint although that amendment was not curative of any deficiency.

In ruling on the motion to dismiss, the district court (Hon. Laura Taylor Swain) agreed with Apotex that the amended complaint stated a cause of action for violation of the Lanham Act. A554-56. The court, however, dismissed the antitrust claim because it erroneously believed that the Food and Drug Administration Amendments Act (FDAAA) immunized the filing of sham citizen petitions. A551-54. The court said Apotex failed—at the pleading stage—to make an "evidentiary proffer" that Acorda's citizen petition held up approval of Apotex's drug application in light of the FDAAA even though Apotex alleged that FDA simultaneously denied Acorda's petition and approved Apotex's ANDA.

A553. Absent such an "evidentiary proffer", the court concluded that the complaint failed to allege an antitrust injury. A554.

At the time, the parties were operating under the Pilot Project Regarding Case Management Techniques for Complex Civil Cases in the Southern District of New York (Pilot Rules). A30. Under those rules, a party wanting to file a motion has to send a letter, not to exceed three pages, to the court requesting a pre-motion conference. A46. Apotex sent such a letter in advance of filing a motion for leave to file a second amended complaint to provide further allegations regarding antitrust injury. A580-82. This would be Apotex's first curative amendment. A268-69.

At the pre-motion hearing, Acorda convinced the court that it had given Apotex proper advance notice that the FDAAA allegedly barred Apotex's antitrust claim such that Apotex should be precluded from any amendment. A615 at 15:5-16. Acorda, however, had provided no such notice. A587. But based on that misinformation, the court summarily converted Apotex's pre-motion letter into a motion for leave to file a second amended complaint and then summarily denied that "motion". A614-15 at 14:23-15:20. The court did not issue a written opinion. A8 (D.I. 54).

Later, following discovery on the false-advertising claim, Acorda sought summary judgment. A631-36. The district court (Hon. Analisa Torres, who took

the case over from Judge Swain), granted Acorda's motion. SPA1-19. Instead of viewing Acorda's advertising as a whole, the court consistently engaged in what this Court has called "disputatious dissection", *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001) (internal quotation omitted), pulling apart the various individual strands to assess the falsity and/or materiality of each component strand in isolation. SPA6-7. By focusing on only the individual tiles of Acorda's promotional materials, the court failed to appreciate the way they work together in service of the overall mosaic of Acorda's literally false message that Zanaflex Capsules provide the benefit of reduced somnolence.

The court still found that a jury could deem a key part of Acorda's advertising literally false, but it ruled, contrary to this Court's explicit precedent, that Apotex also had to show that Acorda's literally false statements were likely to influence consumers' purchasing decisions. SPA14-15. And the court overlooked that Apotex had in fact produced evidence showing that the false advertising *did* affect purchasing decisions.

This appeal followed.

STATEMENT OF THE FACTS

Since this appeal is from the dismissal of Apotex's antitrust claim and summary judgment on its Lanham Act claim, this statement of facts reflects the

amended complaint's allegations with respect to the former and the record evidence with respect to the latter.

Development of Zanaflex Capsules.

Acorda bought the tizanidine franchise from Elan Pharmaceuticals, which first sold tizanidine tablets in 1996 under the trade name "Zanaflex". A271-72 at ¶¶9, 10, 17. Faced with the looming expiration of its exclusivity to Zanaflex tablets, Elan sought ways to extend its Zanaflex monopoly and thwart generic competition. A271-72 at ¶11. It settled upon reformulating Zanaflex into capsules. *Id.*

To help secure exclusivity to the capsules, Elan sought a patent, but it could not obtain a patent covering tizanidine capsules per se. A2348. Instead, Elan obtained U.S. Patent No. 6,445,557 (the '557 patent), which claimed only methods of using tizanidine capsules. A272 at ¶¶14-16, 2395, 2403.

Elan also applied to FDA for approval to market tizanidine capsules. A272 at ¶12. As part of its application, Elan included the results of a clinical study—protocol AN021-101 (the 101 study)—which assessed, among other things, the pharmacokinetic property known as Cmax (each subject's highest amount of drug in the bloodstream following administration), incidences of side effects such as somnolence (a well-known and pervasive side effect of tizanidine, A644 at col. 2,

645 at col. 2), and how much, if at all, the drug slowed the subjects' reaction times. A272 at ¶13, 3456-57, 3462-65.

The 101 study failed to show tizanidine capsules provide the benefits of reduced somnolence or Cmax.

The 101 study was a 96-subject four-way crossover study, meaning there were four treatment arms such that over the course of the study each subject took Zanaflex tablets with food (treatment A) and without food (treatment B) and tizanidine capsules with food (treatment C) and without food (treatment D). A3454-56.

The study's administrators took blood samples at preset times during each treatment arm so that they could measure Cmax and other pharmacokinetic parameters. A3456-57.

As Acorda has admitted, the 101 study found no statistically significant differences in Cmax among the four treatment arms. A2571 ("No significant differences in Cmax, AUC, and t1/2"), 2636 ("The only statistically significant difference is in tmax."), 2647 ("It is important to remind the audience that with the exception of Tmax, no other statistically significant between group differences were found."), 2680 at 125:4-10 ("Q. Fair enough. And the 101 study in fact did not conclude that there was a statistically significant difference in the Cmax or the peak plasma concentration between administering the capsules in the fed state and any other arm of the study; is that correct? A. That's correct.").

Put otherwise, the 101 study showed no scientifically provable difference in Cmax between the capsules and the tablets whether taken with or without food. A2763-72 at ¶¶16-50. So any apparent differences are highly likely (95% probability) due to pure chance as opposed to any properties of tizanidine capsules or tablets. *Id.*, A2735-36 at ¶42.

The 101 study also listed the adverse events (side effects) that the study participants reported. A3462-65. However, the study was not designed or powered to detect differences in adverse events between the four treatment arms. A3468. Nevertheless, Acorda conducted an after-the-fact analysis of the adverse-event data to try to tease out differences between the four treatment arms. *Id.* This effort failed to show any statistically significant differences in somnolence. A3468-77, 2733 at ¶36, 2763-66 at ¶¶16-26.

Finally, the participants in the 101 study were subjected to a battery of cognitive tests—primarily reaction-time tests—that were meant to serve as a means of measuring somnolence. A3457. Once again, the study failed to find any statistically significant differences in cognitive impairment among the four treatment arms. *Id.*, A3466, 2733-34 at ¶37, 2772 at ¶¶47-50.

If, then, the goal of the 101 study was to show that tizanidine capsules reduced somnolence and Cmax, it was a bust. The study failed to show that tizanidine capsules were in any way superior to Zanaflex tablets or generic

tizanidine tablets. A2242-43 (FDA concluding it's "unclear if the capsule provides any clinical benefit over the tablet"), 2441 ("In conclusion, the Zanaflex Capsule has **NOT** demonstrated any improved efficacy or safety benefits over the tablet dosage form...") (emphasis in original).

FDA approves tizanidine capsules but concludes that the 101 study does not support claims to reduced somnolence.

FDA reviewed the 101 study and concluded that the study failed to demonstrate that tizanidine capsules reduce somnolence. A2227 ("The sponsor believes that less variation in the PK [i.e., pharmacokinetic] profile (in the presence and absence of food) for the capsule will have the clinical benefit in providing a more consistent pharmacological and safety profile. *This has not been established in the present NDA*.") (emphasis added), 2242 ("[O]verall cognitive impairment … produced by each treatment, irrespective of time, was not significantly different between the four treatments.").

In addition, FDA questioned the reliability of the study's Cmax data. A2332 ("Inspection of the [pharmacokinetic] data reveals a large number of missing subjects. In addition, the statistical analysis may not have been performed correctly."), 2230 ("[F]or the PK-PD study the assay did not perform acceptably and the pharmacokinetic metrics generated cannot be considered accurate."). As a result, while FDA approved Elan's drug application in 2002, Acorda admits that FDA did not and still does not allow Acorda to "affirmatively promote that

Zanaflex Capsules ... yield the benefits of reduced Cmax and reduced somnolence, because such statements are not explicitly included in the approved labeling." A3621.

Acorda acquires the tizanidine franchise and embarks on a false-advertising campaign for Zanaflex Capsules.

Acorda later bought from Elan the fading tizanidine franchise, which included the '557 patent and both Zanaflex tablets and the as-yet unnamed and unmarketed capsules. Because tizanidine capsules offered no proven clinical benefit over Zanaflex tablets (e.g., A2242-43, 2441, 2423), Acorda had to contrive ways to distinguish the two in order convince doctors to switch their patients from tablets to the pricier capsules. E.g., A2481-82.

Acorda knew that Elan had tried to obtain FDA's permission to sell the capsules under a different trade name from "Zanaflex" ("Neuzana"), but FDA refused Elan's request because the active ingredient in the capsules and tablets is the same. A2445. So Acorda had to call its new product Zanaflex Capsules.

Plan B for Acorda was to urge FDA to allow it to provide consumers with separate package inserts or labels for Zanaflex Capsules and Zanaflex tablets. A2482, 2503 at 42:16-43:4. But FDA rebuffed this request as well. A643-46. As such, Acorda was stuck with a product that shared the same trade name as Zanaflex tablets, shared the same product label as Zanaflex tablets, and was therapeutically indistinguishable from the tablets. A2242-43, 2441.

So Acorda turned to the 101 study and used it as the basis of an aggressive sales and marketing strategy whose cornerstone was convincing doctors to believe its false claim that the more-expensive Zanaflex Capsules were superior to both Zanaflex tablets and generic tizanidine tablets because they offered patients the benefit of reduced somnolence. A2482. Given FDA's prohibition on marketing Zanaflex Capsules as reducing somnolence, Acorda touted the alleged (but also unproven) reduction in Cmax as a proxy for promoting reduced somnolence. A2531, 2535, 3327-28, 3538-39, 3541. In this manner, Acorda hoped to exploit doctors' general expectation that Cmax and side effects may have some correlation, although no such correlation was ever proven here because the 101 study showed no statistically significant reduction in somnolence or Cmax.

Acorda's marketing strategy consisted of both oral statements (through sales representatives) and written statements (through promotional materials) falsely touting these supposed benefits of Zanaflex Capsules.

Acorda's sales representatives make false statements about supposed benefits of Zanaflex Capsules.

Acorda's sales representatives told doctors across the country that their patients would experience less somnolence if they used Zanaflex Capsules as opposed to tablets. E.g., A1519, 1522, 1525, 1527-28, 3072, 3093. The representatives also repeatedly used Cmax (the "PK profile" or the "graph") as a proxy for somnolence. E.g., A1516, 1520, 1522-23, 3074. The capsules, said

Acorda's sales reps, offer greater flexibility over—and are therefore superior to—Zanaflex (or generic tizanidine) tablets because they don't make patients drowsy. E.g., A1522-23, 1525, 3074. These statements appear in several successive reports where Acorda's sales representatives describe their marketing efforts and the feedback they received from doctors and their staff. The following are some representative statements:

September 2005 Report

> [The doctor] was not aware of the Capsule, but said that he had already prescribed Zanaflex twice that morning. *I discussed the PK levels, side effects*, and making sure that he writes "Capsules" on the prescription.

A1516 (emphasis added).

> [The doctors were] interested in learning about Zanaflex capsules and *the possibility that there would be less sedation with the capsules* when taken with food so that their patients could spread their medication out over the day. Their main questions were the price of the capsules versus the tablets….

A1519 (emphasis added).

> I asked [the doctor] about the most common complaint with Zanaflex tablets and *he said the drowsiness and then we went to the graph and I discussed the capsules* (which is how I love a call to work out).

A1520 (emphasis added).

> [The doctor] thinks the new *Zanaflex Capsule* will be great for her patients who currently take the tablets ... *because they are active in the day and it will keep them from becoming completely sedated.*

A1522 (emphasis added).

> The physicians state they primary [sic] recommend it at night with their patients due to the sedative effect. Once again we refer to the PK profile and the fact that only the Zanaflex Capsules give them the benefit of dosing flexibility.

A1522-23.

> I told [the doctor] about the *possibility of 1/3 less side effects with the capsules*. He said that he prescribes Zanaflex at night because of the somnolence that is associated with the tablets. I explained to him that now his patients can have *relief the entire day*, not just at night.

A1525 (emphasis added).

> [The doctor] had some concerns about the price of Zanaflex Capsules.... [T]he cost for a 10 day supply is about $105.00 compared to $35.00 for tablets. He said they were too expensive and he sees this being a problem. *My goal is to justify the cost comparison by selling him on the possibility of the patient having fewer side effects and less sedation*.

A1527-28 (emphasis added).

October 2005 Report

> [The doctors] mentioned that they've been using Norflex and Flexeril with their patients. *Upon learning of the ability to decrease somnolence in using with food, by using Zanaflex Capsules, the doctors agreed to give it a try*.

A3072 (emphasis added).

> Several physicians are utilizing two different products. For example, Zanaflex at night, and Skelaxin during the day. In these situations, the representatives have really been hitting on the *PK profile* of the capsules when taken with food and without food, which *provides flexible dosing* that can in turn eliminate the need for the physician to write for two different products—one product, one script—Zanaflex Capsules.

A3074 (emphasis added).

December 2005 Report

> [The doctor] still prefers the tablets because of his dosing flexibility. He said he can give them a 4 mg and at night they can break it in half and only take 2 mg's and they won't get as drowsy. *I explained to him that the capsules are really unique in that it counteracts a lot of the drowsiness* when you dose it with food.

A3093 (emphasis added).

As these examples show, Acorda's sales representatives made false and misleading statements to physicians that Zanaflex Capsules offer the benefit of reduced somnolence. A2752-54 at ¶¶76-77. And when not saying outright that the capsules reduce somnolence, the representatives touted the supposed—but never scientifically proven—"benefit" of reduced Cmax, which they used as a bridge to convince doctors that their patents would experience reduced somnolence. E.g., A1516, 1520, 1522-23, 3074.

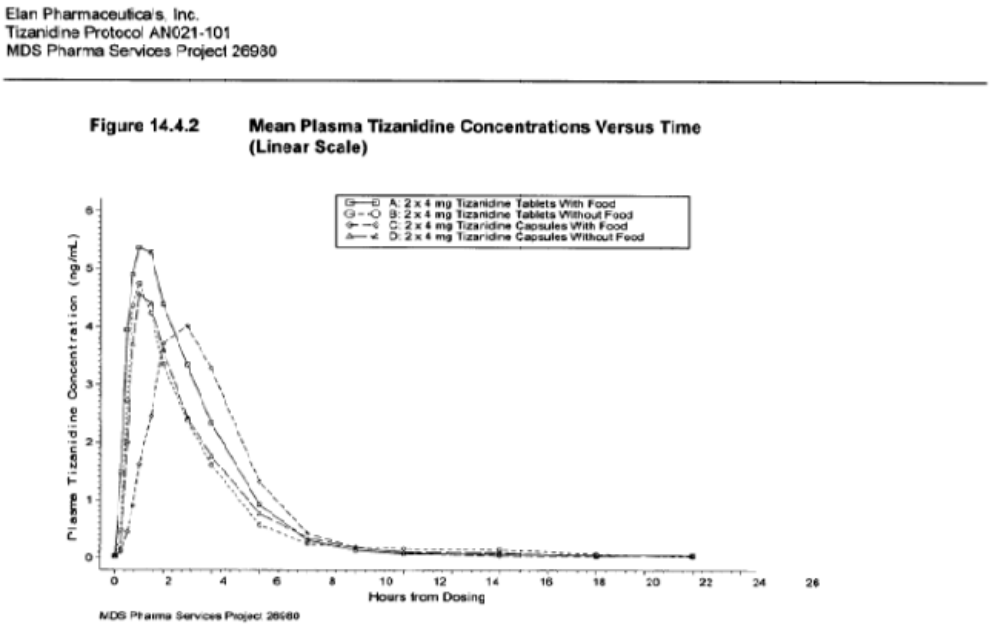
Acorda reinforces its false and misleading claims about Zanaflex Capsules in its written promotional materials.

Acorda's written promotional materials reinforce the sales representatives' false message that Zanaflex Capsules offer the benefit of reduced somnolence. A2731-52 at ¶¶33-75. Consistent with its oral presentations, Acorda's written materials also promote reduced somnolence via the proxy of supposedly reduced Cmax.

Most prominently, Acorda's promotional materials misrepresent that the highest point of curves from the pharmacokinetic data of the 101 study represent

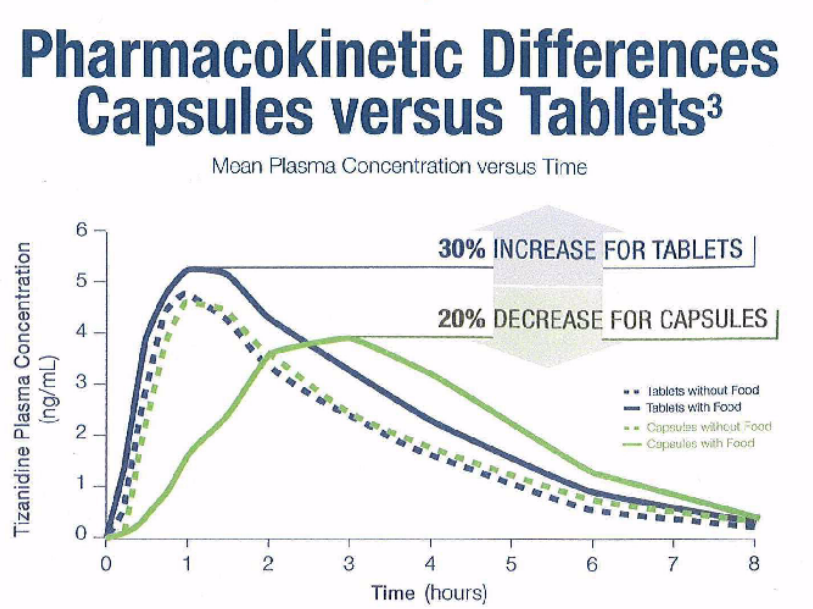
Cmax, and then unjustifiably treat that misrepresentation of Cmax as a proxy for how much somnolence a patient will experience.

The data from the 101 study that Acorda manipulates is the following graphic:



A3452, 2745 at ¶60. These curves show only the mean blood concentration of the drug over all the participants in the 101 study at the predetermined sampling times. A2736-37 at ¶¶43-46. As even Acorda's expert acknowledged, this mean concentration is different from Cmax, which is the highest level of drug in a given patient's blood at whatever time that peak occurs. A3487-92 at 104:13-109:18. So the highest point on each curve is not Cmax. *Id.*, A2736-37 at ¶¶43-46. Nevertheless, Acorda superimposes purported Cmax data—"30% increase for tablets" and "20% decrease for capsules" (*see* A2425, 3249 (stating 30% and 20%

number are "peak plasma levels" or Cmax))—next to the curves to convey the false impression that the curves do in fact represent Cmax:

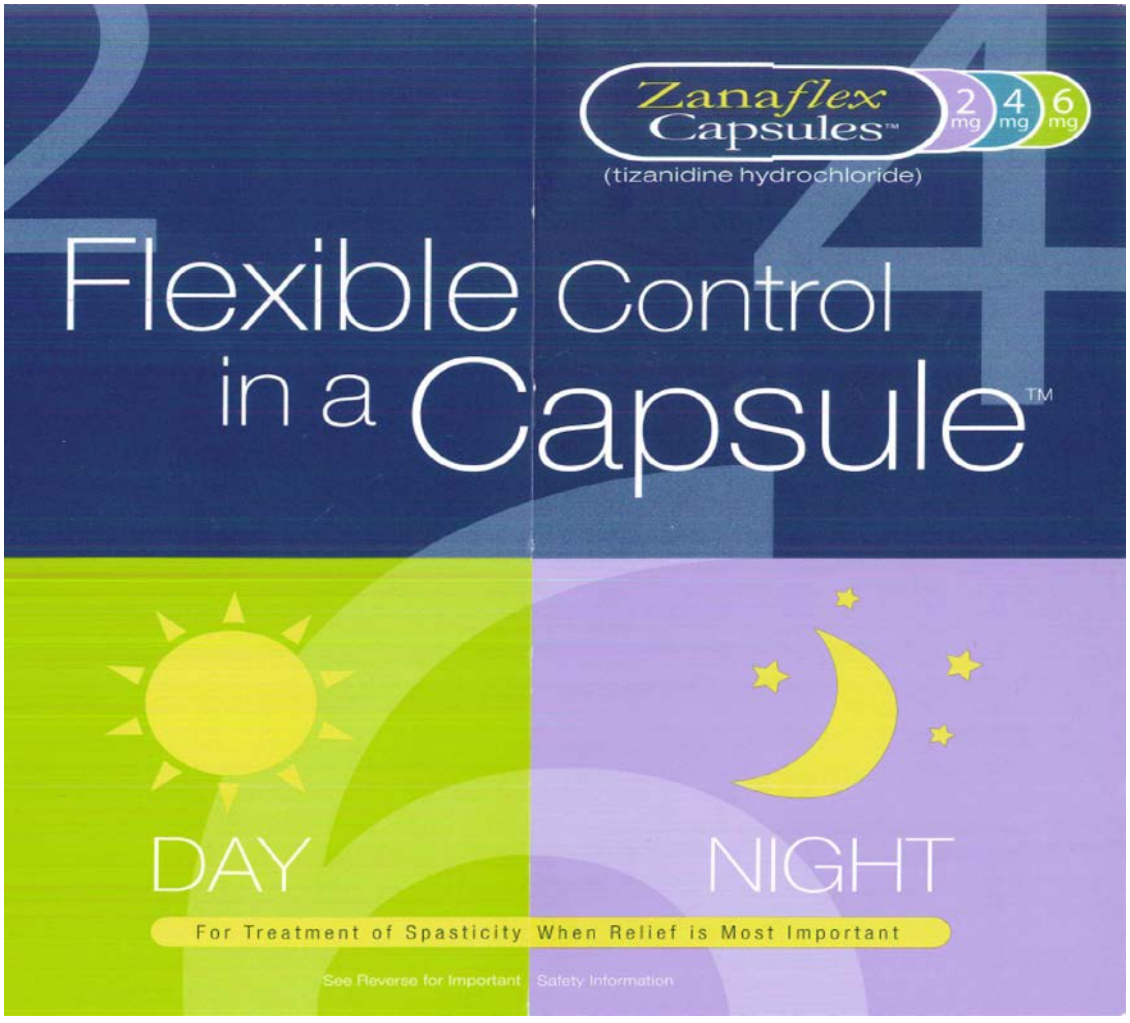


A3249, 3258, 3328, 3378, 3390, 3400, 3411, 2736-46 at ¶¶43-62. By superimposing the "30%" and "20%" language with arrows next to the pharmacokinetic curves and then adding lines running to the top of the curves, Acorda falsely conveys both that the curves represent Cmax levels and that there is a proven difference in those levels between the tablets and capsules. A2736-46 at ¶¶43-62.

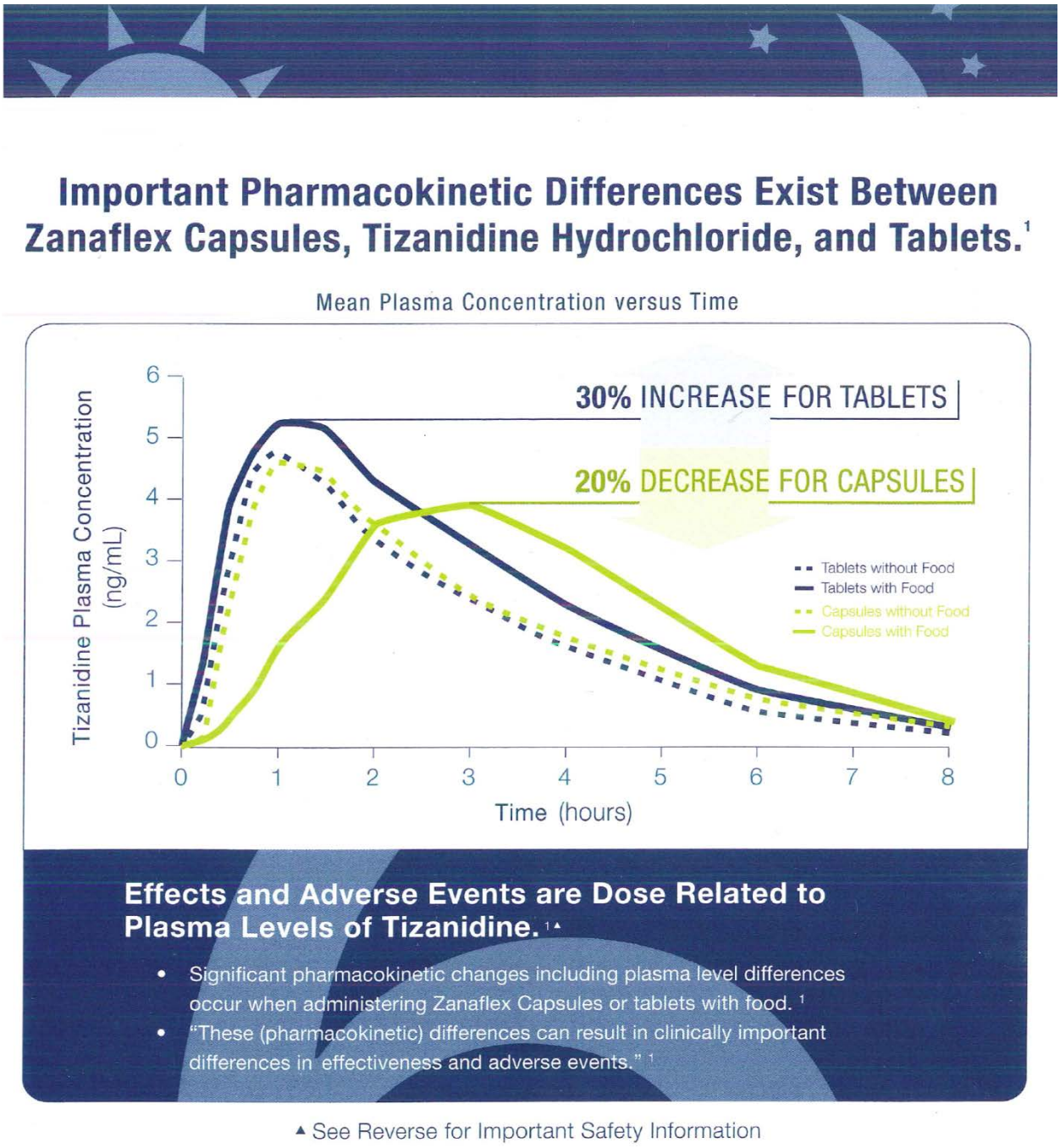
Acorda's promotional materials then add another layer of deception by including text and imagery to play into physicians' general expectation that Cmax and side effects such as somnolence may be related. A2730 at ¶30. Acorda has never established that correlation (e.g., A2224), yet Acorda uses supposedly

reduced Cmax as a springboard to convince doctors that Zanaflex Capsules will lower somnolence.

A conspicuous example of this strategy is Acorda's so-called "gatefold brochure", which Acorda disseminated to 10,000 "targets". A3327-28, 3533, 3503-04 at 159:3-162:14. On the front cover of the gatefold doctors see the message "Flexible Control in a Capsule" as well as images of the sun and moon with the words "day" and "night". A3327. Under that they find the statement: "For Treatment of Spasticity When Relief is Most Important," *id.*:



Id. Opening the flaps of the gatefold reveals the following center panel:



A3328. This panel contains the same false graphic juxtaposing the pharmacokinetic curves from the 101 study with the superimposed textual additions implying proven differences in Cmax. *Id.* Above that graphic, doctors

see the familiar sun-and-moon motif and read: "Important Pharmacokinetic Differences Exist Between Zanaflex Capsules, Tizanidine Hydrochloride, and Tablets." *Id.* Immediately below the graphic, doctors find the statement: "Effects and Adverse Events are Dose Related to Plasma Levels of Tizanidine" followed by two bullet points:

- "Significant pharmacokinetic changes including plasma level differences occur when administering Zanaflex Capsules® or tablets with food." *Id.*
- "These (pharmacokinetic) differences can result in clinically important differences in effectiveness and adverse events." *Id.*

This language of "important" and "significant" differences between capsules and tablets conveys that there are proven (i.e., statistically significant) differences between the two products, especially when juxtaposed with the false image. A2735-36 at ¶¶41-42, 2746 at ¶63. Taken as a whole, the gatefold brochure—with its sun-and-moon imagery and statements about "significant" differences in Cmax and "adverse events" along with the accompanying graphic—unmistakably conveys to doctors that Zanaflex Capsules offer greater flexibility of use: they can be taken during the day with less worry about tizanidine's sedative effect. A2747-51 at ¶¶64-73.

As seen above, however, the 101 study showed no statistically significant difference in Cmax or somnolence between Zanaflex Capsules and Zanaflex or

generic tizanidine tablets. A2571, 2636, 2647, 2680 at 125:4-10, 2733-34 at ¶37, 2751 at ¶73, 2772 at ¶¶47-50, 3466.

Acorda's internal documents regarding the purpose of the gatefold brochure reinforce the conclusion that Acorda's intended message of the piece is that Zanaflex Capsules reduce somnolence. For example, Acorda's "creative brief" for the gatefold states:

> **Does the target audience have any specific motivations, hot buttons or lifestyle issues that should be considered?**
> Some physicians have perception that capsules and tablets are the same and believe that there is a high incidence of AEs mainly somnolence and their patients can not tolerate it during the day.
>
> **Are there attitudes you wish to change?**
> We want to change the perception of physicians who believe that there are no tolerability differences and that they believe that patients can not tolerate Zanaflex during the day. We also want to change the minds of physicians who think Zanaflex Capsules are the same as generic tizanidine.

A3538-39, 2750-51 at ¶¶71-73. Acorda's launch letter to its sales team further explains that the inside center panel of the gatefold brochure will "help" tie supposed differences in Cmax ("PK differences") to supposed differences in "adverse events":

> **Combined PK graph –**
> - Has all 4 treatment groups in one graph with the differences among treatment groups called out.
> - Visually shows the differences in the fed state among the treatment groups further driving home the importance of the PK differences.
> - Demonstrates that these differences can result in clinically meaningful changes in effectiveness and adverse events.
> - Informs physicians that Effectiveness and Adverse Events are dose related to plasma levels of tizanidine.

A3541, 3547 (stating that the gatefold was a "marketing response" to feedback that "[p]hysicians understand Night Time use but need to get across visually the ability to use during the day"), 2750-51 at ¶¶71-73. And Acorda's marketing team specifically advocated creating the "Flexible Control in a Capsule" tagline and tying that into a logo "that symbolizes daytime/bedtime tolerability." A2535.

Acorda's CEO Ron Cohen, discussing the same pharmacokinetic curves shown in the gatefold brochure, said that physicians who view the curves can "immediately intuit" that Zanaflex Capsules, with their lower Cmax profile, may work better for patients during the day. A3587-88, 3600-01. It is this "intuition" that Acorda consistently exploited when misrepresenting a supposed "Cmax" graph as a proxy for somnolence.

Acorda's false advertising resulted in more than $240 million in sales.

Acorda's false advertising worked to convert patients to Zanaflex Capsules. Acorda has enjoyed sales in excess of $240 million on the capsules even though they offered no scientifically proven benefit over the less expensive tablets. A2242-43, 2441, 3705.

Acorda sues Apotex on the '557 patent.

Apotex has sold generic tizanidine tablets since 2004. A275 at ¶29, 1778 at 75:16-76:4. In 2007, Apotex filed an ANDA seeking FDA approval to sell generic tizanidine capsules. A275 at ¶30. Apotex's ANDA certified that Acorda's '557

patent was invalid and would not be infringed by Apotex's product. *Id.* at ¶31. This certification triggered Acorda's prospective infringement action against Apotex, which Acorda filed in 2007, alleging that Apotex's proposed tizanidine capsules, if and when sold, would infringe the '557 patent. *Id.* at ¶32.

In May 2011, the district court for the District of New Jersey (Hon. Garrett E. Brown, Jr.) held a seven-day bench trial on the patent-infringement case. *Id.* at ¶33. On September 6, 2011, the court ruled that Acorda's '557 patent is invalid and not infringed by the use or sale of Apotex's proposed product. *Id.* at ¶33.

Acorda files a citizen petition that FDA denies as "without merit".

The moment Acorda lost the patent trial it filed a citizen petition with FDA asking the agency not to approve Apotex's ANDA. *Id.* at ¶34. Citizen petitions are meant to allow persons or entities to express genuine concerns to FDA about the safety of a product or about scientific or legal issues concerning a product either before or after the product is on the market. 21 C.F.R. § 10.30. FDA permits any entity to file a citizen petition asking the agency to take, or not take, any administrative action. A276 at ¶35, 21 C.F.R. §§10.25(a), 10.30.

Although many citizen petitions raise legitimate concerns, brand pharmaceutical companies have realized that by filing citizen petitions at or near the time of generic entry they can delay final ANDA approval—and thereby

extend their lucrative monopolies—while FDA evaluates whether the petitioner's arguments have any merit. As the former chairman of the FTC observed in 2006:

> [The citizen petition process] is susceptible to systemic abuse.... It is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions are denied.

Jon Liebowitz, How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry (but only in Opposition to the FTC's Position on Exclusion Payment Settlements), http://www.ftc.gov/sites/default/files/documents/public_statements/how-settlements-make-strange-bedfellows-or-how-federal-trade-commission-has-managed-unite-entire/060929gphapubvers_0.pdf at 2-3. Not surprisingly, brand companies' misuse of the citizen-petition process has given rise to antitrust claims due to its anticompetitive nature and effect. *See, e.g., In re DDAVP Direct Purchasers Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009); *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07 Civ. 7343, 2008 WL 169362 (S.D.N.Y. Jan. 18, 2008).

In an effort to address this anticompetitive abuse, Congress passed the FDAAA, enacted in 2007. A581. These amendments provide, in part, that FDA shall not delay approval of a pending ANDA because of a citizen petition unless FDA determines that a delay is necessary to protect the public health. 21 U.S.C. §

355(q)(1)(A)(ii). If such a delay is necessary, FDA will delay the ANDA approval until the public-health concern is resolved. 21 U.S.C. § 355(q)(1)(B).

Congress was obviously uncertain that the FDAAA's enactment would eradicate the citizen-petition abuse problem as it included in the statute a requirement that FDA submit an annual report to Congress detailing how often and by how long the pendency of citizen petitions delayed the agency's ANDA approvals during the year. 21 U.S.C. § 355(q)(3).

In fact, as the agency itself has acknowledged, the FDAAA's enactment has not solved the abuse problem. A581-82, 599; *see also* Michael Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 281-83 (2012) ("[W]hat is clear is that the 2007 amendment has not been successful in achieving its stated purposes."). This is because the statute has a soft spot that brand companies exploit, namely, the fact that it is impossible for FDA to immediately determine whether a citizen petition implicates issues of public health. Rather, the agency has to undertake a careful review of the citizen petition to make even that initial determination. A581, 596. That preliminary review itself takes time, and during that time, FDA is loath to approve an ANDA lest the petition actually turn out to raise a public-health concern, which would necessitate a costly and difficult product recall. *Id.* As a practical matter FDA must review even a baseless citizen petition to determine whether the issues it raises legitimately affect

public health or safety. 21 U.S.C. § 355(q)(1)(B), A581-82, 596. That baseless petition can therefore delay approval of an ANDA during that initial review despite the best intentions of the FDAAA. A581-82, 596.

On February 3, 2012, FDA denied Acorda's citizen petition, concluding that Acorda's arguments were "without merit". A276 at ¶39, 414-20.

Acorda's citizen petition delayed generic competition.

FDA approved Apotex's ANDA the very day it denied Acorda's citizen petition, which Apotex has alleged demonstrates that the petition's filing and pendency delayed competition in the tizanidine-capsules market. A277 at ¶¶43-44. If, as Apotex has alleged, Acorda had not filed its meritless petition, Apotex's ANDA could have been approved—and Apotex could have entered the market—before February 3, 2012. A275 at ¶34, 277 at ¶45.

Upon FDA approval, Apotex immediately launched its tizanidine capsules. A277 at ¶45. In response, Acorda launched an "authorized generic" version of its Zanaflex Capsules. A277-78 at ¶46. Apotex alleged that Acorda strategically chose the time to launch its authorized generic product to cause maximum harm to Apotex. *Id.* The launch of the authorized generic, the complaint alleges, further buttresses the conclusion that Acorda filed its citizen petition not out of a concern for "public safety", but rather to destroy competition in the market for tizanidine capsules. A277-78 at ¶¶46-47.

Apotex alleged that as a direct result of Acorda's unlawful conduct, for at least five months consumers were denied Apotex's lower-priced tizanidine capsules and were forced instead to buy Acorda's monopoly-priced Zanaflex Capsules. A278 at ¶47.

SUMMARY OF THE ARGUMENT

1. Under this Court's precedent, Apotex's amended complaint stated a plausible antitrust injury. Apotex alleged that Acorda filed a sham citizen petition that FDA denied the same day it approved Apotex's generic product. Apotex further alleged that the sham petition was intended to and did delay FDA's approval of Apotex's generic tizanidine capsules and that, as a result, Acorda delayed competition in the tizanidine-capsule market in violation of the antitrust laws.

This Court has held that a complaint states a plausible antitrust injury when it alleges that FDA approved the generic product at the same time it denied a citizen petition and that the simultaneity of these actions reinforces the possibility that the petition delayed generic competition sufficient to require denial of a motion to dismiss. The district court in the case at bar failed to follow this precedent.

Moreover, the district court committed legal error in holding that Congress's enactment of the FDAAA—which provides that a citizen petition shall not delay

approval of a generic drug unless it implicates public health—precluded antitrust liability for filing a sham citizen petition here. As other courts and FDA itself have recognized, notwithstanding the FDAAA, branded firms can still delay generic approval for the time it takes FDA to consider and decide *whether* the citizen petition identifies a genuine issue of public health, regardless of whether the petition actually does or does not. It was therefore reversible error for the court to interpose the FDAAA as a presumptive cure-all on a motion to dismiss where the amended complaint alleged facts that, taken as true, establish that Acorda's citizen petition delayed generic competition in the market for tizanidine capsules.

2. Assuming for argument's sake the amended complaint somehow failed to allege an antitrust injury, the district court erred in denying Apotex leave to make its first curative amendment. Under the Pilot Rules for complex cases, Apotex was required to and did submit a short pre-motion letter announcing its intention to seek leave to amend. But at a status hearing, the court announced that it would treat that short letter as a motion for leave to amend and would deny leave. The court's errors were three.

First, there is no authority in the Pilot Rules or anywhere else for precluding a party from filing a motion for leave to amend, as the court effectively did. By foreclosing proper briefing, the court deprived itself of the benefit of a discussion

of the Rule 15 amendment standards. As a result, the court did not even mention, much less analyze, these standards in denying leave.

Second, the court made a factual error when it held that amendment would be precluded because Apotex had proper advance notice of Acorda's FDAAA argument. Under the Pilot Rules, the only recognized mechanism for providing that advance notice is a letter from the moving party preceding its motion to dismiss. Acorda's letter did not even allude to the FDAAA, much less argue that it immunized Acorda from antitrust liability based on a sham citizen petition.

Third, the court apparently did take note of at least some of Apotex's proposed new allegations, but failed to accept those allegations as true, which obviously is not permitted in ascertaining whether a complaint would state a cause of action.

3. The record contains abundant evidence of the literally false advertising message that Zanaflex Capsules offer the benefit of reduced somnolence. The district court, however, consistently failed to follow this Court's requirement to view the challenged advertising as a whole rather than engage in fine dissection of the promotional message.

By pulling apart the various components of Acorda's oral and written promotional presentations, the court lost sight of Acorda's central message and the means Acorda used to convey it. That is, Acorda knew that doctors generally

expect that the Cmax of a drug is related to its side effects such that if you reduce Cmax enough you *may* be able to reduce side effects as well. Acorda has no proof that this general expectation holds true in the case of Zanaflex Capsules, and indeed it has test results demonstrating that this is not the case. Nor does Acorda have any scientific proof that Zanaflex Capsules actually reduce Cmax. Nevertheless, Acorda's sales representatives and promotional materials unqualifiedly assert that Zanaflex Capsules meaningfully reduce Cmax and somnolence. In this regard, Acorda often exploits doctors' general expectation that Cmax and side effect may be related (a relationship that was never established with respect to Zanaflex) by using Cmax as a proxy for somnolence to convince doctors that Zanaflex Capsules provide the benefit of lower somnolence.

A prime example of Acorda's false advertising is its gatefold brochure, which combines a literally false "Cmax" graph with selective words and images to connote that Zanaflex Capsules are amenable to daytime use, i.e., induce less somnolence, when that benefit has never been established. Had the district court viewed Acorda's promotional materials as a whole, it would not have lost sight of the primacy of Acorda's message about reduced somnolence, a message that a reasonable jury could have found literally false.

The district court took note of the brochure's day-and-night imagery but found it ambiguous, postulating three other possible messages the court said it

might convey about extended release or long-term relief. In doing so, the court impermissibly overlooked Acorda's own internal memos establishing that the very goal of the gatefold brochure was to assuage doctors' concerns about the side effect of somnolence and to convince them that it was beneficial to prescribe Zanaflex Capsules for daytime use. On Acorda's motion for summary judgment the court was required to believe Apotex's evidence, not ignore it, and had to resolve any perceived ambiguities in Apotex's favor.

Finally, although the court held that a jury could find part of Acorda's messaging literally false, the court legally erred in holding that Apotex was required to, but failed to, produce evidence that the literally false advertising would have an effect on consumers. This Court recently clarified and reaffirmed, in a decision the district court did not acknowledge, that a Lanham Act plaintiff that shows that an advertisement is literally false *need not* also establish its effect on consumers. In any event, even if the district court's erroneous burden of production existed, Apotex satisfied it with evidence of Acorda's sales of Zanaflex Capsules as a result of its promotional campaign—money consumers spent on a product that offers no proven benefit over tablets that are less expensive.

ARGUMENT

I. Apotex's amended complaint adequately alleges an antitrust injury.

Under this Court's precedent, Apotex's amended complaint sufficiently stated a plausible antitrust injury when it alleged, among other things, that FDA approved Apotex's ANDA on the same day it denied Acorda's citizen petition and that the petition therefore delayed competition in the relevant market. *In re DDAVP*, 585 F.3d at 694; *Louisiana Wholesale Drug*, 2008 WL 169362 at *6 ("A valid antitrust injury would be an injury to the consumers whose power of choice was impaired as a result of Defendants' conduct.") (citing *Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 182 (S.D.N.Y. 2006)).

In deciding a motion under Rule 12(b)(6), the court must "construe the complaint in the light most favorable to the plaintiff, accepting the complaint's allegations as true." *Todd v. Exxon Corp.*, 275 F.3d 191, 197 (2d Cir. 2001). A claim may not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id.* at 197-98 (internal quotation marks and citation omitted). This Court reviews *de novo* the grant of a motion to dismiss. *Id.* at 197.

Apotex's amended complaint alleges facts that, taken as true, establish that Acorda's sham citizen petition delayed approval of Apotex's ANDA and, as a

result, delayed competition in the market for tizanidine capsules. Specifically, Apotex's complaint alleges:

- FDA granted final approval of Apotex's ANDA on the same day it rejected Acorda's Citizen Petition. Acorda's baseless Citizen Petition delayed final approval of Apotex's ANDA, allowing Acorda to engage in additional acts in furtherance of its unlawful monopolization scheme. A277 at ¶44.

- Acorda's filing of its Citizen Petition was a baseless sham that delayed the approval and sales of Apotex's tizanidine-capsule product. Through such conduct, Acorda unfairly sought to destroy competition in the tizanidine-capsule market. A278 at ¶47.

- Acorda's anticompetitive conduct had the purpose and effect of unreasonably restraining and injuring competition by protecting the market from generic competition. A280 at ¶59.

- Apotex has been injured in its business and property by reason of Acorda's unlawful monopolization. Apotex's injury consists of being unlawfully delayed in entering the market for tizanidine capsules. A280 at ¶60.

- But for Acorda's illegal conduct, Apotex would have received FDA approval for and begun marketing a generic version of tizanidine capsules earlier than it actually did. A280 at ¶64.

- If Apotex had entered the market and competed with Acorda in a full and timely fashion, prescribers, patients, and other purchasers would have substituted Apotex's lower-priced generic tizanidine capsules for Acorda's higher-priced Zanaflex Capsules and/or would have received lower prices on some or all of their remaining Zanaflex Capsule purchases. A280-81 at ¶65.

Taking these allegations as true, as is required on a motion to dismiss, *Todd*, 275 F.3d at 197, Apotex's complaint adequately alleges that Acorda's anticompetitive conduct delayed Apotex's entrance into the tizanidine-capsule market thereby forcing consumers to pay supra-competitive prices for Acorda's Zanaflex Capsules longer than they otherwise would have had to. This is a

quintessential antitrust injury. *See In re DDAVP*, 585 F.3d at 688 (holding that forcing purchasers of a brand-name drug to pay supra-competitive prices as a result of company's anticompetitive conduct "plainly is 'of the type the antitrust laws were intended to prevent'") (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)); *Louisiana Wholesale Drug*, 2008 WL 169362 at *6.

Indeed, in *In re DDAVP*, this Court recognized that allegations like those here—FDA's simultaneous rejection of the defendant's citizen petition, on the one hand, and approval of the plaintiff's ANDA, on the other—reinforce the "possibility that the sham petition caused a delay in generic competition" sufficient to require denial of a motion to dismiss a Sherman Act antitrust claim. *In re DDAVP*, 585 F.3d at 694.

Nevertheless, the district court required Apotex to go beyond alleging an antitrust injury when it demanded that Apotex make, on a motion to dismiss, an "evidentiary proffer" to establish affirmatively that Acorda's sham citizen petition delayed competition in the tizanidine-capsule market. A553. In so holding, the court failed to appreciate that the simultaneity of FDA's denial of Acorda's petition and approval of Apotex's application *is* evidence that this Court has accepted as establishing that the two were intertwined. *In re DDAVP*, 585 F.3d at 694.

The district court erroneously believed that, in light of the FDAAA, it would be "[in]appropriate[]" to "infer that any delay in approval of Plaintiffs' ANDA was caused by Defendant's citizen petition." A553-54. But the allegations of Apotex's amended complaint not only required the district court to "infer" that very fact, but also to accept it as true. *Todd*, 275 F.3d at 197.

Moreover, the district court's analysis is predicated on a flawed understanding of the FDAAA. The court assumed that because of the FDAAA's language that a citizen petition must not delay approval of an ANDA unless it raises a genuine issue of public health, Acorda's petition could not possibly cause a delay. But as discussed earlier, it takes time for FDA to make even its initial review to determine *whether* a petition raises a legitimate public health concern. A581, 596. It is the delay caused by *that* preliminary review that is at issue in this case. That is the soft spot in the FDAAA that we mention above that brand companies continue to exploit. *Id.*

FDA itself has admitted that abuse and delays persist in the wake of the FDAAA and that a scarcity of resources limits the agency's ability to comply strictly with Congress's requirement that a citizen petition not delay approval of an ANDA. A581-82, 596-99. Try as it might, FDA is not always capable of following the FDAAA to the letter. *See* Michael Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 283 (2012) ("[T]o date,

the amendment has not reduced the number of unsuccessful (in other words, denied or essentially denied) citizen petitions that appear to be filed to delay generic competition."). The district court's decision allows brand companies to continue to exploit that inability for their own benefit and to the detriment of the drug-buying public.

Other courts have recognized that the FDAAA has not cured the abuse problem and that anticompetitive delays based on the filing of baseless citizen petitions persist post-2007 giving rise to potential antitrust liability. For instance, in a case involving a citizen petition filed after enactment of the FDAAA, the Federal Circuit held that the suspicious timing of the petition—filed the day after the patentee lost a patent case (just like Acorda did here) and a week before FDA could approve the ANDA—could be found to have caused FDA to delay the approval of an ANDA. The court reversed summary judgment against the generic company on the citizen-petition issue, directing the district court to "determine whether Mutual suffered an anticompetitive harm in the form of a delay in the approval of its ANDA due to the filing of Tyco's citizen petition with the FDA." *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1348 (Fed. Cir. 2014). At no point did the Federal Circuit suggest that the FDAAA foreclosed Mutual's antitrust claim.

Likewise, in *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litigation*, __ F. Supp. 3d __, No. 13-MD-2445, 2014 WL 6792663 (E.D. Pa. Dec. 3, 2014), the court held that a complaint stated a plausible claim of antitrust injury when it alleged that the filing of a citizen petition delayed generic approval. The court specifically rejected the proposition that the FDAAA's enactment meant that the filing of a citizen petition could cause no regulatory delay. The court recognized what the district court here failed to recognize—that "a branded firm may still be able to delay generic approval while the FDA considers whether the relevant Citizen Petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition is [a] sham or not." *Id.* at *19 (quoting complaint allegation).

In short, these cases demonstrate that the FDAAA does not foreclose the possibility that Acorda's citizen petition delayed FDA approval of Apotex's ANDA and unlawfully blocked competition in the market for tizanidine capsules. Apotex should be afforded the opportunity to demonstrate, following discovery, the effect that Acorda's citizen petition had on the approval of Apotex's ANDA.

If affirmed, the district court's decision would set a dangerous precedent. As we have shown, FDA is aware that, despite enactment of the FDAAA, brand companies continue to file baseless citizen petitions to block generic competition, even if they stand to gain only the time it takes FDA to determine whether the

petition raises a public-health concern. Generic companies, judges, and legal scholars are also aware of this weakness in the statutory scheme that brand companies exploit to the detriment of the American consumer. The district court's decision effectively immunizes brand companies from antitrust liability for abusing the citizen-petition procedure. That is not and should not become the law of this Circuit.

II. The district court erred in refusing to allow Apotex even to file a motion for leave to file a second amended complaint and in denying leave.

As we've shown, Apotex's amended complaint adequately alleges an antitrust injury, so there should have been no need for Apotex to file a second amended complaint, which would have been its first curative amendment. Nonetheless, the district court compounded its error by not allowing Apotex to amend its complaint to address and allay the court's concerns, misplaced as those concerns were. In fact, the court committed manifold errors in hurriedly foreclosing Apotex's right to amend. Justice was not done, for many reasons.

First. The district court didn't allow Apotex even to file a motion seeking leave to amend its complaint. After the court erroneously granted Acorda's motion to dismiss, Apotex followed the Pilot Rules and sent a short letter, within the three-page limit, requesting a pre-motion conference in advance of filing a motion for leave to file a second amended complaint to provide further allegations regarding antitrust injury. A580-82. The district court at the pre-motion conference

announced that it was converting Apotex's letter into a motion seeking leave to amend and then summarily denied leave to amend. A614-15 at 14:23-15:3.

The court erred. Nothing in the Pilot Rules forecloses a party from filing a motion for leave to amend, and the pre-motion letter cannot serve as a substitute for a motion. After all, the Pilot Rules limit the pre-motion letter to a scant three pages, A46 at A.2, and obviously do not contemplate a party setting forth a complete legal argument and analysis under Federal Rule of Civil Procedure 15 in that limited space.

In converting Apotex's letter into a motion and foreclosing proper briefing, the court failed to give due, or apparently any, consideration to Rule 15(a), which provides that leave to file an amended complaint "shall be freely given when justice requires," FED. R. CIV. P. 15(a), and should not be denied unless there is evidence of undue delay, bad faith, undue prejudice to the non-movant, or futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962). Apotex had no opportunity to raise these factors in briefing a motion for leave to amend, and, in turn, the court did not properly consider any of these factors. Nor did the court acknowledge that "it is the usual practice upon granting a motion to dismiss to allow leave to replead." *Cruz v. TD Bank, N.A.*, 742 F.3d 520, 523 (2d Cir. 2013) (citing *Cortec Indus., Inc. v. Sum Holding L .P.*, 949 F.2d 42, 48 (2d Cir. 1991)).

Second. The court misunderstood the Pilot Rules and their effect given the facts of this case. Section A.4 of the motion procedures of the Pilot Rules allows a court to consider one of the following options on motions to dismiss:

> (a) Not requiring a pre-motion conference; (b) requiring the parties to exchange letters (with or without a copy to the court) prior to filing a motion to dismiss, addressing any deficiencies in the complaint, in the hope that such deficiencies might be cured by the filing of an amended complaint; or (c) holding a conference after the motion is made at which the plaintiff will be given an opportunity to either amend the complaint or oppose the motion.

A46. The rule also provides that "[i]f plaintiff does not choose to amend, the plaintiff shall be given no further opportunity to amend the complaint to address the issues raised by the pending motion." *Id.*

Here, the parties were operating under option (b). Acorda sent Apotex a letter purporting to address perceived deficiencies in the amended complaint. A587-88. That letter did not even mention the FDAAA, much less raise it as an independent ground for dismissal. *Id.* Instead, the letter offered, as Acorda's only ground for dismissal relating to antitrust injury, the following:

> The antitrust count should be dismissed because Apotex makes no plausible allegation in its Complaint that its failure to bring its generic capsule to market has been caused by anything other than its inability to obtain FDA approval.

Id. This letter did not serve to put Apotex on notice of any issue under FDAAA. There was therefore no basis under the Pilot Rules to trigger the provision precluding further amendment. A46.

Acorda, however, convinced the district judge that Apotex was on notice of its FDAAA argument because Acorda raised it in its motion to dismiss. But Acorda cites no provision in the Pilot Rules or otherwise requiring a plaintiff to withdraw its complaint and seek to amend in the face of a motion to dismiss that the plaintiff does not believe is meritorious. A590-91. Recall, the allegations in the amended complaint tracked *In re DDAVP*, so Apotex had no reason to withdraw that complaint once Acorda filed its motion to dismiss it. *Id.*

Moreover, even if it were relevant whether Acorda mentioned the FDAAA in its motion to dismiss, it did so only obliquely and never argued that the language of the statute itself necessarily foreclosed Apotex's claim. A254, 486, 491. Acorda waited until its reply brief in support of its motion to dismiss to develop an FDAAA argument for the first time—a classic case of sandbagging. A539-40.

The district court thus was mistaken in believing that the FDAAA issue was "very thoroughly ventilated in the briefing on the motion to dismiss." A605 at 5:7-8. But even if the issue had been ventilated on the motion to dismiss, it would not trigger any prohibition, in the Pilot Rules or elsewhere, on subsequent amendment.

Third. Ultimately, the court took note of at least some of the allegations that Apotex proposed to add. But in doing so, the court engaged in legally improper weighing of their credibility and apparently concluded that amendment would be futile. For example, Apotex's letter proposed amendments to the complaint to

allege that FDA informed Apotex that it was awaiting resolution of the citizen petition in order to approve Apotex's ANDA. A581. Yet the district court dismissed this allegation as a "vague assertion[] that somehow the FDA communicated that there was a delay." A615 at 15:5-16. At the pleading stage, the court was required to lay skepticism aside and accept this straightforward allegation as true. Further, Apotex's proposed amendments discussed FDA's published reports to Congress about abuse of the citizen-petition process continuing despite enactment of the FDAAA. A581-82. These allegations the court dismissed as "a strained reading of the FDA's annual report." A615 at 15:5-16. Again the court was weighing the allegations against Apotex, the exact opposite of the proper approach at the pleadings stage.

Where, as apparently was the case here, a district court denies leave to amend based on the belief that amendment would be futile, review is *de novo*. *See, e.g.*, *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012). Accordingly, review here should be *de novo*.

Nevertheless, reversal is required under any standard of review. An abuse of discretion occurs when the district court's decision is based on a misapplication of law or a clear error of fact. *See Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001) (citing *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990)). Here, the court both misapplied the law by failing even to evaluate the

Rule 15 amendment standards and committed a clear error of fact by believing that Apotex had proper notice under the Pilot Rules of the FDAAA issue. The court therefore abused its discretion.

In sum, if the amended complaint were somehow deficient, the court should have allowed Apotex to file its motion seeking leave to file its first curative amendment and ultimately should have allowed that amendment.

III. Genuine disputes of material fact require submitting Apotex's Lanham Act claim to a jury.

Apotex presented abundant record evidence that Acorda's sales team and its promotional literature falsely represented, in both words and images, that Zanaflex Capsules will impart the unproven benefit of reduced somnolence. Acorda itself acknowledges that the study on which its promotional messages were based did not show any statistically significant reduction in either somnolence or Cmax, yet Acorda represented over and over again that Zanaflex Capsules impart these beneficial properties and are therefore superior to the cheaper Zanaflex tablets and generic tizanidine tablets.

This Court reviews *de novo* a grant of summary judgment. *See Smith v. County of Suffolk*, 776 F.3d 114, 121 (2d Cir. 2015). In ruling on Acorda's motion, the district court was required, but failed, to view all evidence in the light most favorable to Apotex. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S.

133, 151 (2000). This includes "resolv[ing] all ambiguities and draw[ing] all permissible factual inferences" in Apotex's favor. *Smith*, 776 F.3d at 121.

Two overarching errors infect the district court's grant of summary judgment, entered without oral argument. First, the district court consistently violated this Court's command to view the accused advertising mosaic as a whole and not to engage in a "disputatious dissection" of each tile pried loose from the mosaic. *S.C. Johnson & Son*, 241 F.3d at 238 (internal quotation omitted). Second, the district court committed legal error in requiring, contrary to this Court's holding in *Merck Eprova AG v. Gnosis S.P.A.*, 760 F.3d 247 (2d Cir. 2014), that Apotex produce evidence that Acorda's literally false advertising influenced consumers' purchasing decisions. *See id.* at 256 ("[W]here a defendant's advertising of products is literally false, a Lanham Act plaintiff need not provide evidence of actual consumer confusion ... in order to establish entitlement to damages under the Lanham Act.")

To establish false advertising under Section 43(a) of the Lanham Act, a plaintiff has to show that the challenged promotional statement is false. 15 U.S.C. § 1125(a). "Falsity may be established by proving that (1) the advertising is literally false as a factual matter, or (2) although the advertisement is literally true, it is likely to deceive or confuse customers." *S.C. Johnson & Son*, at 238 (internal quotation marks omitted). In this Circuit, "in addition to proving falsity, the

plaintiff must also show that the defendants misrepresented an inherent quality or characteristic of the product." *Id.* (internal quotation marks omitted).

Where the advertising involves test-proven superiority, i.e., the "defendant's ad explicitly or implicitly represents that tests or studies prove its product superior, plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited." *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992) (citing *McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991)).

Advertising can be literally false without containing any specific, individual false sentence. This Court has adopted the doctrine of "false by necessary implication," which requires evaluating "the message conveyed in full context," including words, pictures, and how they work together. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). Where, as here, the clear meaning of the advertising statement, considered in context, is unmistakably false, literal falsity has been established. *Id.*

A. A trier of fact could find that Acorda's sales representatives falsely promoted Zanaflex Capsules as providing the benefit of reduced somnolence.

In analyzing the presentations of Acorda's sales representatives, the district court artificially separated the representatives' statements about Cmax from their statements about somnolence and considered the falsity of each standing alone.

SPA7-12. In doing so, the court overlooked that the sales representatives told doctors outright that Zanaflex Capsules reduce somnolence. And the court also lost sight of the way the sales representatives held out Cmax as a proxy for somnolence in an effort to exploit physicians' general expectation that the Cmax and side effects of a drug may be related such that if you reduce a drug's Cmax, you may also reduce its side effects.

The evidence shows that that general expectation is unproven here. That is, the 101 study, which Acorda uses to support its promotional statements, failed to show any statistically significant reduction in Cmax, A2227, 2242, 2571, 2636, 2647, 2680 at 125:4-10, 2735-36 at ¶42, 2763-72, and Acorda admits that neither the 101 nor any other study demonstrates that Zanaflex Capsules reduce somnolence, A3466, 3468, 2733-34 at ¶¶36-37, 2763-66 at ¶¶16-26, 2772 at ¶¶47-50. Nevertheless, Acorda's sales representatives, often invoking Cmax as a proxy for somnolence, told physicians that Zanaflex Capsules provide the benefit of lower somnolence. E.g., A1520 ("I asked [the doctor] about the most common complaint with Zanaflex tablets and he said the drowsiness and then we went to the graph and I discussed the capsules (which is how I love a call to work out).").

In focusing on the trees instead of the forest, the district court failed to grasp or appreciate Acorda's exploitation of the perceived (but never proven) interdependence of Cmax and somnolence in imparting Acorda's central sales

message—that Zanaflex Capsules provide the benefit of reduced somnolence. That in itself requires reversal. But even looking separately at the salespersons' statements about Cmax and somnolence as the district court did, summary judgment was not warranted.

Reduced Cmax. The court held as a matter of law the sales representatives' statements regarding the benefits of reduced Cmax were consistent with the Zanaflex product label, SPA8, but ample evidence supports the opposite conclusion—that the representatives' statements were not consistent with the label. For example, the sales representatives told doctors that the pharmacokinetic profile of Zanaflex Capsules (here, the Cmax) gives doctors "the benefit of dosing flexibility" (A1522-23) or "provides flexible dosing" that allows patients to take the capsules both during the day and at night (A3074). By contrast, the product label says nothing about lower Cmax resulting in any benefit. Nor does the label say that Zanaflex Capsules offer any "flexibility" over tablets. A trier of fact could therefore find that the representatives' statements are not supported by the label. A2752-54 at ¶¶76-77. At minimum, the significance of the representatives' indisputable departures from the product label is a question for the trier of fact to resolve, and not for a court to determine as a matter of law after viewing the evidence in the light most favorable to the summary judgment movant.

Reduced somnolence. The district court properly concluded that Acorda's sales representatives told doctors that Zanaflex Capsules impart the benefit of reduced somnolence and that these were commercial statements. But the court erred when it determined that "none of the sales representatives' statements regarding somnolence involve claims of test proven superiority." SPA11.

This latter conclusion is demonstrably wrong. The court itself cited case law noting that a promotional claim involves "test-proven superiority" where it "'make[s] statements while pointing to *graphs* or similar items.'" *Id.* (quoting *Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharm. Co.*, 935 F. Supp. 327, 329 (S.D.N.Y. 1996) (emphasis added)). The court then "acknowledge[d] that some of the challenged statements refer to a *graph* of pharmacokinetic differences between Zanaflex Capsules and tablets." SPA12 at n.1 (emphasis added). This should have ended the inquiry as to whether the claims involve test-proven superiority. The court, however, found the claims not to involve test-proven superiority by improperly inferring—against the non-movant Apotex—that Cmax and somnolence were not intertwined in the sales message and that the sales representatives were not using Cmax as a proxy for somnolence.

This error is particularly puzzling here where in the very example the district court cited, the sales representative explicitly says that when the doctor complained about Zanaflex tablets causing drowsiness, she immediately referred him "to the

[pharmacokinetic] graph." *Id.* In other words, to support the conclusion that that the sales representatives did *not* use the pharmacokinetic graph to show levels of somnolence, the court cited an example where a sales representative *did* use the pharmacokinetic graph to show levels of somnolence.

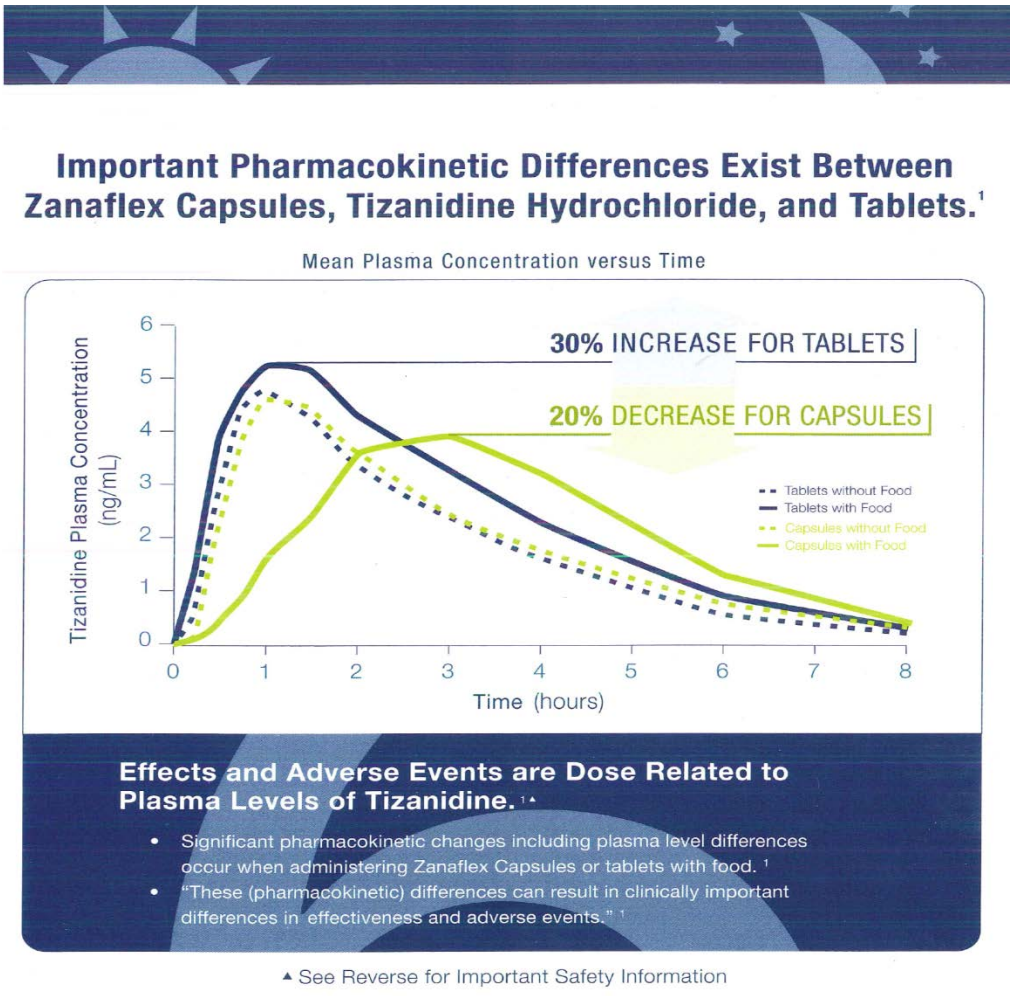
Further, the district court's conclusion was inconsistent with its own acknowledgment that promotional claims of test-proven superiority may be implicit as well as explicit. SPA11 (quoting *Castrol*, 977 F.2d at 63). While here Apotex produced evidence of the sales representatives' explicit references to graphs (e.g., A1516, 1520, 1522-23, 3074), the promotional claims also *necessarily* implied test-proven superiority. After all, to claim the capsules reduce somnolence (or Cmax) necessarily implies that they reduce somnolence as compared to some other product and that, in turn, data exist to support the comparison.

Finally, assuming we are dealing with claims of test-proven superiority, Apotex also adduced the necessary evidence of falsity, namely that the testing that has been conducted on Zanaflex Capsules does not establish the proposition that Zanaflex Capsules result in the benefit of reduced somnolence, as Acorda itself has admitted. A3466, 3468, 2733-34 at ¶¶36-37, 2763-66 at ¶¶16-26, 2772 at ¶¶47-50.

B. A trier of fact could find that Acorda's promotional materials likewise falsely promoted Zanaflex Capsules as providing the benefit of reduced somnolence.

The district court held, correctly, that a reasonable juror could find that the graphic that is at the heart of many of Acorda's written promotional materials is literally false. SPA14-15. But by not viewing Acorda's promotional materials as a whole, the court failed to appreciate how Acorda used this graph and all of the surrounding messages to convey the overarching false message that Zanaflex Capsules reduce somnolence—a claim that Acorda concedes is unproven.

As Acorda's chairman candidly admitted, Acorda knew and expected that doctors viewing that graphic would "immediately intuit" that Zanaflex Capsules may work better for patients during the day. A3587-88, 3600-01; *S.C. Johnson & Son*, 241 F.3d at 238 ("[W]e have explicitly looked to the visual images in a commercial to assess whether it is literally false."). This literally false graphic is the centerpiece of Acorda's gatefold brochure:



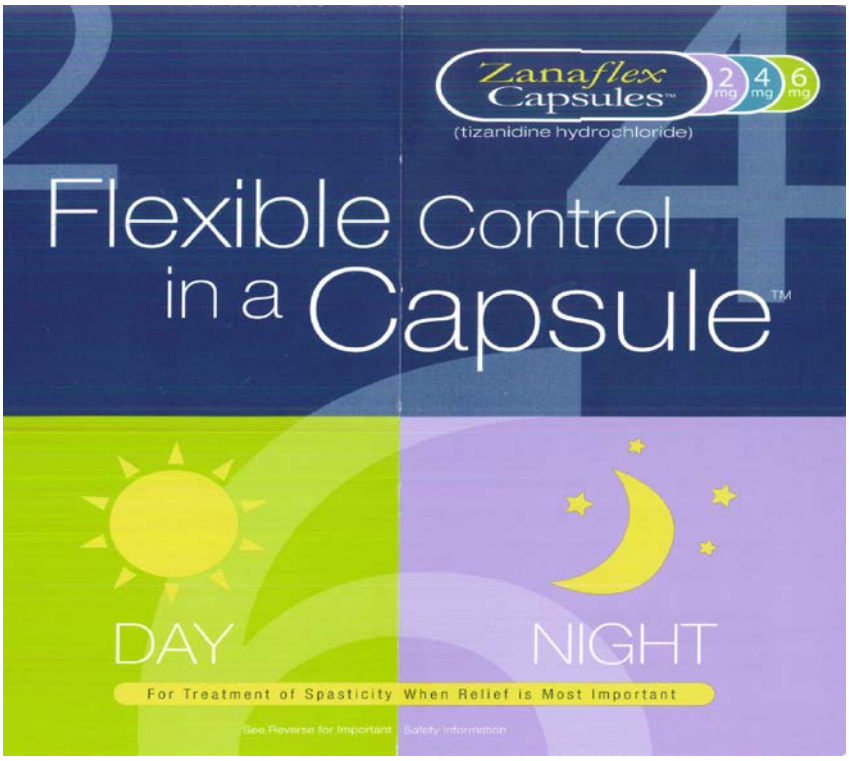
A3328. It is this graphic (or one very similar to it) that Acorda's sales representative immediately showed a doctor when the doctor complained that Zanaflex tablets made his patients drowsy, A1520; Acorda, in other words, unjustifiably treats the "Cmax" curves (which don't represent Cmax at all, A2736-37 at ¶¶43-46) as a proxy for drowsiness. The messages that surround the graphic—"important ... differences"; "effects and adverse events are dose related"; "significant ... changes"—all reinforce the message conveyed by the literally false graph itself that there are meaningful differences between Zanaflex Capsules and

Zanaflex (or generic tizanidine) tablets. A2747-49 at ¶¶65-69. But Acorda has admitted that the 101 study failed to show any meaningful—i.e., statistically significant—differences in somnolence or Cmax (e.g., A2680 at 125:4-10, 3466, 3468), and for purposes of false-advertising liability under the Lanham Act, studies that purport to support claims made in promotional materials must be statistically significant. *See McNeil-P.P.C.*, 938 F.2d at 1549-50 (plaintiff demonstrated that the study supporting superiority claim was not statistically significant).

The *McNeil* case, which involves closely analogous facts, provides the appropriate analytical roadmap. There, McNeil, which made Tylenol, sued Bristol-Myers, which made Excedrin, claiming that Bristol-Myers falsely advertised that AF Excedrin provided better pain relief than ES Tylenol. *Id.* at 1546. McNeil relied on a study that Bristol-Myers had conducted that established that AF Excedrin did not relieve pain better than ES Tylenol to a statistically significant degree. *Id.* This Court agreed with the district court that McNeil's use of the defendant's own study was sufficient to establish the falsity of the superiority claim where the study did not show a statistically significant difference. *Id.* at 1549; *see also American Home Prods. v. Johnson & Johnson*, 577 F.2d 160, 169 n. 19 (2d Cir. 1978) (court disregarded non-statistically significant studies); *Coors Brewing Co. v. Anheuser-Busch Cos.*, 802 F. Supp. 965, 973-74 (S.D.N.Y. 1992) (court disregarded consumer survey because it was not statistically

significant); *Philip Morris Inc. v. Loew's Theatres, Inc.*, 511 F. Supp. 855, 857-58 (S.D.N.Y. 1980) (advertising based on consumer preference is false when supporting study lacking statistical significance). If the evidence adduced in *McNeil* was sufficient to sustain a *judgment for the plaintiff*, the same evidence here was certainly sufficient to avert *summary judgment* for the defendant.

Moreover, the graph and the messages surrounding it are of a piece with—and cannot be viewed in isolation from—the cover of the gatefold brochure, which includes images of the sun and moon above the words day and night and accompanied by the tagline "flexible control in a capsule", thereby reinforcing the central false message that Zanaflex Capsules reduce somnolence:



A3327.

A doctor whose patients complain that Zanaflex tablets make them drowsy during the day picks up the gatefold piece and is greeted with the suggestion that *capsules* are "flexible" and that that flexibility means that (unlike tablets) they can be taken at night *and* during the day. The doctor then opens the flaps on the gatefold and immediately (and most prominently) sees the literally false graphic surrounded by words that unqualifiedly trumpet "significant" and "important" differences between capsules and tablets. The doctor, as discussed above, has a general preconceived expectation that Cmax and side effects are related, and the doctor knows—because she already prescribes Zanaflex or tizanidine tablets—that somnolence is one of the most prominent side effects associated with tizanidine. Acorda exploited this expectation and crafted the gatefold so that the doctor sees the graph as representing levels of somnolence and concludes, based on the totality of the gatefold, that Zanaflex Capsules reduce somnolence.

It does not take speculation to conclude that Acorda intended to use the gatefold brochure—including the "Cmax" graph, the sun/moon/day/night graphic, and all of the other language in the brochure—to convey the false message that Cmax and somnolence are linked with respect to Zanaflex Capsules and ultimately that the capsules provide the benefit of reduced somnolence. We know that because Acorda has said so in its internal marketing "creative brief", where Acorda readily admits that the goal of the gatefold brochure was to "change the

perception" of doctors who think their patients "can not tolerate Zanaflex during the day" because of the "high incidence of AEs [i.e., side effects] mainly somnolence." A3538-39, 2750-51 at ¶¶71-73. And in an internal launch letter to its sales team, Acorda clarified that the gatefold will "help" by using the "PK graph" to "demonstrate[] ... clinically meaningful changes [between Zanaflex Capsules and tablets] in ... adverse events." A3541, 2750-51 at ¶¶71-73.

Recall, too, that the gatefold brochure and similar written materials were tools that Acorda's salespeople used when they would visit physicians. A1516, 1520, 1522-23, 3074. As shown earlier in the excerpts from the sales staff's reports, any time a sales person mentioned Cmax or pharmacokinetic properties, it was part and parcel of an effort to convince the doctor that Zanaflex Capsules offer the benefit of reduced somnolence as compared to Zanaflex or tizanidine tablets. *Id.*

Although the district court recognized that a juror could find the graphic literally false, it failed to grasp this overall message the gatefold conveys because—as with Acorda's sales representatives' statements—the court erroneously pulled apart each separate strand of the brochure instead of viewing the overall tapestry of the advertisement. The court analyzed the front cover of the brochure separately from the inside (SPA14, 15-17); analyzed the image on the inside of the brochure separately from the statements surrounding the image

(SPA14, 17-18); and analyzed the statements surrounding the image separately from one another (SPA17-18). At no time did the district court endeavor to discuss the overall message imparted by the totality of the words and images in context and considering the intended audience. Simply put, the district court let context yield to text. *See Time Warner*, 497 F.3d at 157 ("'Fundamental to any task of interpretation is the principle that text must yield to context.'") (quoting *Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986)).

This fundamental error infected the entirety of the court's analysis and led to manifold additional errors. For instance, the court viewed the sun-and-moon imagery and certain statements about pharmacokinetic differences in isolation and determined that part of the message to be ambiguous, postulating that it *could* mean that Zanaflex Capsules "relieve symptoms throughout the entire day" or "release the drug in a controlled manner" or "allow for more effective treatment of spasticity over time." SPA16. In so speculating, the court had to have ignored the evidence, specifically Acorda's "creative brief" and launch letter, which make crystal clear that Acorda's goal in disseminating the gatefold brochure was to promote Zanaflex Capsules as reducing somnolence. A3541, 3538-39, 2750-51 at ¶¶71-73. It was palpable legal error for the court to make up, whole cloth, supposed alternative interpretations of the message conveyed in the gatefold

brochure while ignoring actual evidence produced by the nonmovant showing that the alternative interpretations were baseless.

Moreover, each of the court's potential "alternative" interpretations of the supposedly ambiguous sun-and-moon imagery is itself inconsistent with basic facts about Zanaflex Capsules and therefore not reasonable. *See Time Warner*, 497 F.3d at 158 (language or graphic cannot be literally false only if it "is susceptible to more than one *reasonable* interpretation") (emphasis added). Zanaflex Capsules are immediate release, not controlled or extended release, and so a doctor would know that they neither "relieve symptoms throughout the entire day" nor "release the drug in a controlled manner." E.g., A2396 at "Abstract", 2224 ("short-acting drug for the treatment of spasticity"). And there is no evidence that Zanaflex Capsules "allow for more effective treatment of spasticity over time." E.g., A2242-43, 2441. Regardless, on Acorda's motion for summary judgment, the court was not entitled to resolve ambiguities, even if there were any, against Apotex. *See Smith*, 776 F.3d at 121. A trier of fact could certainly interpret Acorda's message, as reflected in the whole of the brochure and Acorda's internal memos describing its purpose, to be that Zanaflex Capsules offer more flexibility because they lower somnolence.

The court's dissection of Acorda's promotional materials was also so pervasive that it led the court to separately analyze "Reduced Cmax – Promotional

Materials" and "Pharmacokinetic Differences – Promotional Materials" even though the only pharmacokinetic parameter at issue is Cmax. SPA13-15, 17-18. And when analyzing the claims to so-called pharmacokinetic differences, the court lost sight of the fact that these statements—nestled as they are above and below the graph comparing capsules and tablets, A3328—are quintessential claims of test-based superiority. As such, the court erred in requiring Apotex to "affirmatively prove" that the claims are false. *See Castrol*, 977 F.2d at 63; *McNeil-P.P.C.*, 938 F.2d at 1549.

The court's slice-and-dice approach also led it to overlook Acorda's consistent practice of omitting important qualifying language, the absence of which renders Acorda's statements literally false. In each instance where a statement in Acorda's promotional materials differs from a statement in the package insert, the promotional message omits important qualifying language found in the package insert. Acorda's promotional materials, for instance, state unequivocally that "Effects and Adverse Events *are* Dose Related to Plasma Levels of Tizanidine." A3328 (emphasis added). The package insert, however, says only that effects *appear* to be dose-related to plasma levels. A645 at col. 2 (emphasis added). Similarly, Acorda's affirmative promotional message is that "Significant pharmacokinetic changes including plasma level differences *occur* when administering Zanaflex Capsules® or tablets with food." A3328 (emphasis added).

Yet here, too, the package insert equivocates, saying only that pharmacokinetic differences *may* result in clinically significant differences. A646 at col. 2 (emphasis added). And several of Acorda's promotional materials state unequivocally that taking Zanaflex or generic tizanidine tablets with food increased Cmax by exactly 30% as compared to taking that same drug without food. A3249, 3328, 3378, 3390, 3400, 3411. But the package insert does not make such a bald statement; it states that the increase is *approximately* 30%. A643 at col. 1.

Without fail, Acorda's promotional statements remove the necessary qualifying language of the package insert and replace it with unwarranted and untrue affirmative statements of fact. *See Merck Eprova AG v. Gnosis S.P.A.*, 901 F. Supp. 2d 436, 454 (S.D.N.Y. 2012) (holding that the defendant's use of specific nomenclature in its marketing pieces materially misrepresented that its product was a pure form when really it was a mixture of forms and thus its advertisement was literally false), *aff'd* 760 F.3d 247 (2d Cir. 2014); *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1317 (11th Cir. 2010) (finding that limiting qualifying language that an independent testing company used in a report did not support the conclusions drawn in the defendant's advertisements and therefore the statements made in the ads regarding the safety and efficacy of the product were literally false).

The district court also erroneously concluded that Apotex failed to present evidence affirmatively proving the falsity of Acorda's promotional claim to reduced somnolence. SPA17. The 101 study itself, as Acorda admits, failed to show any statistically significant differences in somnolence or Cmax. E.g., A2680 at 125:4-10, 3466, 3468; *McNeil* (plaintiff may rely on defendant's study to show data disproving comparison claims). The 101 study therefore *is evidence* that there are no significant or important differences between Zanaflex Capsules and tablets. On summary judgment, the court was supposed to credit this evidence.

Finally, even if, despite all the facts and law above, Acorda's promotional claims can somehow be viewed as not literally false, at the very least they are misleading for all the reasons stated above, or so a trier of fact could find. In that event, the record also contains the necessary evidence of consumer confusion to sustain a Lanham Act claim. Specifically, Acorda's Chief Commercial Officer and Rule 30(b)(6) witness, Lauren Sabella, confirmed that Acorda's sales of Zanaflex Capsules were due to Acorda's focus on the supposed benefits discussed above. She testified that Acorda's promotional message was consistently focused on pharmacokinetics (i.e., Cmax) to convince doctors to go "through the hurdles that they have to go through in order to get authorization to use a drug [Zanaflex Capsules] that's more expensive than a generic…." A2817-18 at 76:18-77:4. Moreover, Sabella acknowledged that what moved doctors to prescribe Zanaflex

Capsules was the "primary message" of "pharmacokinetic differences". A1909 at ¶27. And Acorda's internal surveys confirmed that doctors were receptive of an alternative to Zanaflex or tizanidine tablets that reduced the side effect of somnolence. E.g., A3223, 3300-03. Further still, the evidence indicates that patients bought in excess of $240 million worth of Zanaflex Capsules even though they offered no scientifically proven benefit over the less expensive tablets. A2242-43, 2441, 3705; SPA5; *Reed Const. Data Inc. v. McGraw-Hill Companies, Inc.*, No. 09-CV-8578 JPO, 2014 WL 4746130, at *23 (S.D.N.Y. Sept. 24, 2014) ("To sustain a claim under the misleadingly-false theory of the Lanham Act, a plaintiff need only show—using whatever evidence—that a substantial number of consumers were, in fact, confused by the allegedly misleading statement.").

In sum, the district court's analysis underscores the wisdom of the requirement to view the defendant's promotional materials as one mosaic. By failing to do that, the court missed not only outright false statements, but also distinct patterns and relationships between Acorda's various representations that would permit a trier of fact to view Acorda's promotional message as false.

C. The district court committed legal error in requiring Apotex to produce evidence that Acorda's literally false message would influence consumers' purchasing decisions, but Apotex produced such evidence in any event.

The district court committed further legal error in ignoring this Court's recent clarification of the law of false advertising. In *Merck*, this Court reaffirmed

in no uncertain terms that "where a defendant's advertising of products is literally false, a Lanham Act plaintiff need not provide evidence of actual consumer confusion ... in order to establish entitlement to damages under the Lanham Act." 760 F.3d at 256. *Merck* relied on *Time Warner* for the proposition that "[w]hen an advertisement is shown to be literally or facially false, consumer deception is presumed, and the court may grant relief without reference to the advertisement's [actual] impact on the buying public." 497 F.3d at 153 (internal quotation omitted).

Instead of applying this unequivocal precedent, the district court held precisely the opposite: that despite showing literal falsity of the central graphic in Acorda's promotional materials, Apotex also had to show "that the alleged inaccuracy in the statements at issue would influence the purchasing decisions of consumers." SPA15. This error appears to be based on the district court's misunderstanding of the concept of materiality. In this Circuit, one proves materiality by "show[ing] that the defendants misrepresented an inherent quality or characteristic of the product," *Merck*, 760 F.3d at 255 (internal citation and quotation omitted), not by showing that the literally false misrepresentation would influence purchasing decisions. And here there can be no reasonable doubt that representations that Zanaflex Capsules offer the benefit of reduced somnolence—

i.e., of how the capsules behave in the body once ingested—are representations about an inherent quality or characteristic of Zanaflex Capsules.

The errors in the district court's analysis were thus many. First, the court applied an erroneous materiality standard. Second, the court erred in limiting its "materiality" analysis to just the one tile of Acorda's promotional mosaic that the court viewed as literally false. Third, upon finding evidence that Acorda's graphic was literally false, it was error to require Apotex to show that the graphic also would influence consumers' purchasing decisions.

Finally, even if Apotex were required to show that Acorda's false advertising "would" influence consumers' purchasing decisions, as noted above Apotex showed that the false advertising *did in fact* influence consumers' purchasing decisions. Again, Acorda's Sabella confirmed that Acorda's sales of Zanaflex Capsules were due to its promotional message. A1909 at ¶27, 2817-18 at 76:18-77:4. And Acorda's sales of Zanaflex Capsules exceeded $240 million even though they offer no benefits over tablets. A2242-43, 2441, 3705. Viewing this evidence in the light most favorable to Apotex, a trier of fact could readily infer that Acorda's false and misleading sales pitch had its intended effect—to spur doctors concerned with somnolence to prescribe the more expensive product in an effort to alleviate this unwanted side effect in their patients.

* * *

The abundant evidence discussed above shows that Apotex has created genuine issues of fact regarding Acorda's false advertising. Apotex has a right, under the Seventh Amendment and Rule 56, to have all questions of fact resolved by a jury, not by a district court that impermissibly views the evidence in the light most favorable to Acorda. *See* U.S. CONST. amend. VII; FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Feingold v. New York*, 366 F.3d 138, 148 (2d Cir. 2004); *see generally* Suja A. Thomas, *Why Summary Judgment Is Unconstitutional*, 39 VA. L. REV. 139 (2007). Remand is necessary to vindicate that important right.

CONCLUSION

For the above reasons, Apotex respectfully asks that the Court vacate the district court's dismissal of the antitrust claims in Apotex's amended complaint and order the district court to reinstate those claims for further proceedings. At the very least, Apotex should be permitted to amend its antitrust claims.

In addition, or in any event, Apotex respectfully asks the Court to vacate summary judgment on Apotex's Lanham Act claims and reinstate those claims so that a jury can resolve the many disputed issues of fact.

Respectfully submitted,

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March 4, 2015

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, the foregoing brief is in 14-Point Times Roman proportional font and contains 13,873 words and thus is in compliance with the type-volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

Dated: New York, New York
March 4, 2015

Respectfully submitted,
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s/Keith D. Parr
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Counsel for Appellants

SPECIAL APPENDIX

TABLE OF CONTENTS

SPA-1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

APOTEX INC. and APOTEX CORP.,

Plaintiffs,

-against-

ACORDA THERAPEUTICS, INC.,

Defendant.

11 Civ. 8803 (AT)

MEMORANDUM AND ORDER

ANALISA TORRES, District Judge:

In this action, Plaintiffs, Apotex Inc. and Apotex Corp., allege that Defendant, Acorda Therapeutics, Inc., made false and misleading promotional statements about its pharmaceutical product, Zanaflex capsules, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Defendant moves for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. For the reasons stated below, Defendant's motion is GRANTED.

BACKGROUND

Zanaflex tablets and Zanaflex capsules are distinct pharmaceutical products approved by the Food and Drug Administration ("FDA") for the treatment of spasticity. Def. 56.1 ¶ 1, ECF No. 87; Pl. 56.1 ¶ 1, ECF No. 96. The active ingredient in both products is tizanidine. Def. 56.1 ¶ 1; Pl. 56.1 ¶ 1. One of the most common side effects associated with tizanidine is somnolence. Def. Mem. App. A at 3, ECF No. 86-1. Generic versions of Zanaflex tablets were introduced in the United States in 2002. Def. 56.1 ¶ 2; Pl. 56.1 ¶ 2. Plaintiffs began selling a generic version of the tablets in 2004. Def. 56.1 ¶ 2; Pl. 56.1 ¶ 2. In April 2005, Defendant began selling Zanaflex capsules. Def. 56.1 ¶ 3; Pl. 56.1 ¶ 3. The capsules had not been sold prior to April 2005. Def. 56.1 ¶ 3; Pl. 56.1 ¶ 3.

According to the FDA-approved "combined" product label for Zanaflex tablets and Zanaflex capsules (the "FDA label"), the products are not bioequivalent in the "fed state" (*i.e.*,

when administered with food). Def. 56.1 ¶ 5; Pl. 56.1 ¶ 5; *see also* Def. Mem. App. A at 1. The FDA label explains, among other things, that: "[f]ood has complex effects on tizanidine pharmacokinetics, which differ with the different formulations"; "[t]hese pharmacokinetic differences may result in clinically significant differences when . . . switching between the tablet and capsule in the fed state"; and "[t]hese changes may result in increased adverse events or delayed/more rapid onset of activity, depending upon the nature of the switch." Def 56.1 ¶ 10; Pl. 56.1 ¶ 10; *see also* Def. Mem. App. A at 4. The label also notes that "the prescriber should be thoroughly familiar with the changes in kinetics associated with these different conditions." Def. 56.1 ¶ 10; Pl. 56.1 ¶ 10; *see also* Def. Mem. App. A at 4.

On December 2, 2011, Plaintiffs filed the original complaint in this action. An amended complaint, filed on February 21, 2012, alleges that Defendant: (1) engaged in anticompetitive conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2; (2) made false and misleading promotional statements about Zanaflex capsules in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and N.Y. Gen. Bus. Law §§ 349, 350; (3) tortiously interfered with Plaintiffs' prospective business; and (4) was unjustly enriched by its purported misconduct. Am. Compl. ¶¶ 48-96, ECF No. 27. Defendant moved to dismiss the amended complaint. On February 7, 2013, the Honorable Laura Taylor Swain dismissed Plaintiffs' Sherman Act and state law causes of action—leaving only the Lanham Act claim remaining. ECF No. 45.

DISCUSSION

I. Standard of Review

Summary judgment is appropriate when the record shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute exists "if

the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Material facts are those which, under the governing law, may affect the outcome of a case. *Id.*

The moving party bears the initial burden of informing the court of the basis for its motion and identifying those portions of the pleadings, depositions, answers to interrogatories, admissions on file, and other materials in the record that demonstrate the absence of a genuine dispute. Fed. R. Civ. P. 56(a), (c); *Celotex*, 477 U.S. at 323. If the moving party meets its initial burden, the burden then shifts to the non-moving party to establish the presence of a genuine dispute. *Beard v. Banks*, 548 U.S. 521, 529 (2006); *Santos v. Murdock*, 243 F.3d 681, 683 (2d Cir. 2001). The moving party is entitled to judgment as a matter of law where the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof. *Celotex*, 477 U.S. at 322-23.

In ruling on a motion for summary judgment, all evidence must be viewed in the light most favorable to the non-moving party, *Overton v. N.Y. State Div. of Military & Naval Affairs*, 373 F.3d 83, 89 (2d Cir. 2004), and the court must "resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought," *Sec. Ins. Co. of Hartford v. Old Dominion Freight Line, Inc.*, 391 F.3d 77, 83 (2d Cir. 2004). However, the non-moving party may not avoid summary judgment by "rely[ing] simply on conclusory statements." *Burt Rigid Box, Inc. v. Travelers Prop. Cas. Corp.*, 302 F.3d 83, 91 (2d Cir. 2002).

II. Section 43(a) of the Lanham Act

A. Applicable Law

Section 43(a) of the Lanham Act provides a cause of action against

> [a]ny person who . . . uses in commerce . . . any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.

15 U.S.C. § 1125(a)(1). To prevail on such a claim, the plaintiff must "show[] that the challenged advertisement is false and misleading, not merely that it is unsubstantiated by acceptable tests or other proof." *Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (citations omitted); *see also, e.g.*, *Mylan Pharm., Inc. v. Procter & Gamble Co.*, 443 F. Supp. 2d 453, 459 (S.D.N.Y. 2006) ("To establish a false advertising claim under section 43(a) of the Lanham Act, the [p]laintiff must demonstrate that the statement in the challenged advertisement is false."). Two theories are available to a plaintiff seeking to meet this burden. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007). "First, the plaintiff can demonstrate that the challenged advertisement is literally false, *i.e.*, false on its face." *Id.* "[O]nly an *unambiguous* message can be literally false. Therefore, if the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." *Id.* at 158 (internal quotation marks and citations omitted). "Alternatively, a plaintiff can show that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." *Id.* at 153.

A plaintiff invoking the latter theory "must demonstrate, by extrinsic evidence, that the challenged [advertisement] tend[s] to mislead or confuse consumers." *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 112-13 (2d Cir. 2010) (internal quotation marks and citation omitted); *see also*

Time Warner Cable, 497 F.3d at 153 ("[A] district court *must* rely on extrinsic evidence [of consumer deception or confusion] to support a finding of an implicitly false message.") (alteration in original) (internal quotation marks and citation omitted). The plaintiff must produce such extrinsic evidence "even at the summary judgment stage." *Gameologist Grp., LLC v. Scientific Games Int'l, Inc.*, 838 F. Supp. 2d 141, 165 (S.D.N.Y. 2011), *aff'd*, 508 F. App'x 31 (2d Cir. 2013). Extrinsic evidence of consumer confusion ordinarily comes in the form of consumer surveys, "but this is not a hard-and-fast requirement." *Reed Constr. Data Inc. v. McGraw-Hill Cos., Inc.*, 09 Civ. 8578, 2014 WL 4746130, at *23 (S.D.N.Y. Sept. 24, 2014) (explaining that a plaintiff can show consumer confusion "using whatever evidence").

"In the context of pharmaceutical drugs, courts have generally rejected Lanham Act claims based on advertisements that merely repeat labeling information that has been approved by the FDA." *Mylan Pharm.*, 443 F. Supp. 2d at 460; *see also, e.g.*, *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (noting that promotional statements that "comport substantively with statements approved as accurate by the FDA cannot supply the basis for" a Lanham Act false advertising claim); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) (concluding that FDA approval of statements on a product label is "a defense to a competitor's action under the Lanham Act" and explaining that concerns as to the label's content are "to be addressed by the FDA and not by the courts in a Lanham Act suit"); *cf. Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 95 Civ. 7011, 1996 WL 280810, at *13 (S.D.N.Y. May 24, 1996) (suggesting that a district court should not "substitute [its] discretion for that of the FDA in approving package labelling for over-the-counter medications" by second-guessing the accuracy of those labels).

In addition to demonstrating falsity, "the plaintiff must . . . show that the defendant[] misrepresented an 'inherent quality or characteristic' of the product." *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997) (internal quotation marks and citation omitted). "This requirement is essentially one of materiality . . . ." *Id.* "[T]he Second Circuit has explained that satisfying this materiality requirement depends on whether the alleged inaccuracy in the statements at issue would influence the purchasing decisions of consumers." *Mylan Pharm.*, 443 F. Supp. 2d at 462 (citing *Nat'l Basketball Ass'n*, 105 F.3d at 855). "The plaintiff does not need to demonstrate that the defendant's representations actually affected consumer behavior, but rather only that they were likely to have done so." *Id.* at 463.

B. Allegedly False Statements and Images

To survive a motion for summary judgment, a plaintiff need not prove that challenged promotional statements *are* false. *E.g.*, *Merck Eprova AG v. Brookstone Pharm., LLC*, 09 Civ. 9684, 2011 WL 1142989, at *3 (S.D.N.Y. Mar. 17, 2011). However, the plaintiff must show that a reasonable juror *could* reach that conclusion. *See Anderson*, 477 U.S. at 248. In support of this burden, Plaintiffs point to the following statements and images:

- *Reduced Cmax – Sales Representatives' Statements*. Defendant's sales representatives told doctors that Cmax (*i.e.*, the maximum concentration of a drug in the blood after dosing) is reduced when Zanaflex capsules are taken with food. *See* Pl. Statement of Add'l Material Facts ("Pl. Supp. 56.1") ¶¶ 36-45, 49-52, 70, ECF No. 96; Def. Statement of Add'l Material Facts ("Def. Supp. 56.1") ¶¶ 36-45, 49-52, 70, ECF No. 99. Plaintiffs contend that this claim is false. Pl. Mem. 8, 11, ECF No. 95.

- *Reduced Somnolence – Sales Representatives' Statements*. Defendant's sales representatives told doctors that, when taken with food, Zanaflex capsules cause less somnolence than Zanaflex tablets. *See* Pl. Supp. 56.1 ¶¶ 36-45, 49-52; Def. Supp. 56.1 ¶¶ 36-45, 49-52. Plaintiffs contend that this claim is also false. Pl. Mem. 8, 11.

- *Reduced Cmax – Promotional Materials*. Defendant's promotional materials state that taking Zanaflex tablets with food increases Cmax by 30%, whereas taking Zanaflex capsules with food decreases Cmax by 20%. *See, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74. When this information appears in Defendant's promotional materials, it

typically accompanies a graph of mean tizanidine plasma concentration curves over time. *See, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74. Plaintiffs contend that the Cmax percentages are false and that the presentation of these percentages alongside the graph communicates a false and misleading message. Pl. Mem. 18-19.

- *Reduced Somnolence – Promotional Materials.* One of Defendant's promotional pieces—a "gatefold brochure"—includes the tagline "Flexible Control in a Capsule," images of the sun and moon, the words "day" and "night," and information about "Important Pharmacokinetic Differences." *See* Pl. Supp. 56.1 ¶¶ 83-84; Def. Supp. 56.1 ¶¶ 83-84. Plaintiffs contend that this brochure conveys the false and misleading message that taking Zanaflex capsules with food reduces somnolence. Pl. Mem. 22.

- *Pharmacokinetic Differences – Promotional Materials.* Defendant's promotional materials include statements about pharmacokinetic differences between Zanaflex capsules and tablets that differ from those featured on the FDA label, which, according to Plaintiffs, supports a falsity finding. Pl. Mem. 25-26.

The Court addresses each in turn, and concludes that Plaintiffs have failed to adduce sufficient evidence to survive a motion for summary judgment. Accordingly, Defendant is entitled to judgment as a matter of law. *See Celotex*, 477 U.S. at 322-23.

1. Reduced Cmax – Sales Representatives' Statements

Plaintiffs identify a number of instances in which Defendant's sales representatives told doctors that Cmax is reduced when Zanaflex capsules are taken with food. Pl. Mem. 8-11; *see also* Pl. Supp. 56.1 ¶¶ 36-45, 49-52. Defendant does not dispute that its sales representatives made these statements, Def. Supp. 56.1 ¶¶ 36-45, 49-52, but argues that the statements cannot give rise to liability under the Lanham Act because they are consistent with the FDA label. Def. Reply Mem. 1-4, ECF No. 100. The Court agrees with Defendant. The FDA label includes the following information about Cmax:

> When two 4 mg *tablets* are administered with food the mean maximal plasma concentration is increased by approximately 30% . . . . In contrast, when two 4 mg *capsules* are administered with food the mean maximal plasma concentration is decreased by 20% . . . . Consequently, the mean Cmax for the capsule when administered with food is approximately 2/3's the Cmax for the tablet when administered with food.

Def. Mem. App. A at 1 (emphasis added). Defendant's sales representatives' statements concerning Cmax are consistent with the product label. Accordingly, they cannot provide the basis for a Lanham Act false advertising claim. *See, e.g.*, *Mylan Pharm.*, 443 F. Supp. 2d at 460; *Cytyc Corp.*, 12 F. Supp. 2d at 301.

2. Reduced Somnolence – Sales Representatives' Statements

Plaintiffs also identify a number of instances in which Defendant's sales representatives told doctors that, when taken with food, Zanaflex capsules cause less somnolence than Zanaflex tablets. Pl. Mem. 8-11; *see also* Pl. Supp. 56.1 ¶¶ 36-45, 49-52. Again, Defendant does not dispute that its sales representatives made these statements, Def. Supp. 56.1 ¶¶ 36-45, 49-52, but argues that: (1) these statements were "unauthorized, isolated statements . . . [which] cannot give rise to false advertising liability," Def. Mem. 11, ECF No. 86; and (2) even if these statements could give rise to false advertising liability, Plaintiffs have failed to meet their burden of showing that a reasonable juror could find the statements to be false, *see id.* at 19-21. The Court rejects Defendant's first argument, but agrees with the second.

Defendant contends that the statements identified by Plaintiffs are merely "a few isolated statements that depart from company policy," which, according to Defendant, "do not constitute a Lanham Act violation" in the Second Circuit. *Id.* at 11. Defendant adds that "[s]uch statements are, by definition, not part of an organized campaign . . . which means they are not 'promotion' within the meaning of the Lanham Act." *Id.* (internal quotation marks omitted). In support of this proposition, Defendant cites *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48 (2d Cir. 2002). The Court disagrees with Defendant's reading of *Fashion Boutique*. In that case, the Second Circuit did not hold that "unauthorized, isolated statements by sales representatives" "are, by definition, not part of an organized campaign." Def. Mem. 11

(internal quotation marks omitted). Rather, the Second Circuit explained that "the touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market." *Fashion Boutique*, 314 F.3d at 57. Because there was "no evidence to suggest that [twenty-seven oral statements in a marketplace of thousands of customers] were part of an organized campaign to penetrate the marketplace," the Second Circuit concluded that the plaintiff had failed to show that the defendants' actions were "commercial advertising or promotion" under the Lanham Act. *Id.* at 58. Here, based on the evidence submitted, a reasonable juror could find that Defendant's sales representatives' statements were "part of an organized campaign to penetrate the relevant market." *Id.* at 57. Therefore, the Court cannot say as a matter of law that these statements do not constitute "commercial advertising or promotion."

In addition, Defendant argues that "courts will not impose liability where a pharmaceutical company defendant did 'not instruct' its sale[s] representatives to make allegedly false statements and where, after learning that such statements had been made, the company 'followed up with' its sales force 'and reinforced' company policy." Def. Mem. 12 (brackets and citation omitted). According to Defendant, "[t]he Lanham Act does not impose liability for such 'good faith efforts' at compliance." *Id.* (brackets and citation omitted). In support of these contentions, Defendant cites *Procter & Gamble Pharmaceuticals, Inc. v. Hoffmann-LaRoche Inc.*, 06 Civ. 0034, 2006 WL 2588002 (S.D.N.Y. Sept. 6, 2006). The Court does not read *Hoffmann-LaRoche* as broadly as Defendant. In that case, after conducting a four-day evidentiary hearing, considering oral argument, and reviewing the parties' proposed findings of fact and conclusions of law, the court denied the plaintiffs' motion for a preliminary injunction.

Id. at *1. In doing so, the court noted, among other things, that: (1) the evidence suggested that the defendant's sales representatives were not instructed to provide misinformation; (2) only two percent of the sales representatives' call notes supported the plaintiffs' claim; (3) the call notes were made by a "very small percentage of the overall sales force"; (4) "[t]hese representatives were spoken to and the appropriate messaging was reconfirmed"; and (5) the defendant "made a good faith effort to educate its work force" about the relevant data and "what could and could not be fairly said about it." *Id.* at *32. The court in *Hoffmann-LaRoche* did not hold that a plaintiff cannot, as a matter of law, establish a Lanham Act claim under the facts of this case. In any event, making such an assessment here would require the Court to weigh evidence and determine credibility, which the Court is not entitled to do in resolving a motion for summary judgment. *See Anderson*, 477 U.S. at 249. The Court, therefore, rejects Defendant's argument that the sales representatives' statements cannot, as a matter of law, give rise to false advertising liability under the Lanham Act.

This conclusion, however, does not mean that Plaintiffs have made a showing sufficient to survive a motion for summary judgment. Indeed, Plaintiffs must demonstrate that a reasonable juror could find the sales representatives' statements to be false. Plaintiffs contend that, to prove falsity, they need only show that the challenged statements are not supported by statistically significant evidence. Pl. Mem. 30-31. The Court disagrees. Plaintiffs appear to derive this standard from a line of cases involving advertising claims of "test-proven superiority." *Chesebrough-Pond's*, 747 F.2d at 116, 119 (challenged advertisement for New Wondra, a hand and body lotion, stated, *inter alia*: "[D]ermatologists proved it in clinical tests. New Wondra improves the condition of rough dry skin better[.]"); *see also Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 59 (2d Cir. 1992) (challenged commercial for Quaker State

10W-30 motor oil stated, *inter alia*: "[T]ests prove Quaker State 10W-30 protects better than any other leading 10W-30 motor oil."); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1546 (2d Cir. 1991) (challenged advertisement for AF Excedrin, a pain reliever, stated, *inter alia*: "'[I]n doctor supervised clinical studies . . . AF Excedrin was shown to provide greater headache relief' than ES Tylenol.") (brackets omitted). In these cases, where a "defendant's ad explicitly or implicitly represents that tests or studies prove its product superior," the Second Circuit has held that a plaintiff can prove falsity "by showing that the tests did not establish the proposition for which they were cited." *Castrol*, 977 F.2d at 63; *see also, e.g.*, *Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharm. Co.*, 935 F. Supp. 327, 329 (S.D.N.Y. 1996) (explaining that this "less stringent standard" applies where promotional claims "mention 'studies' or 'tests,' or make statements while pointing to graphs or similar items"). "[A] plaintiff can meet this burden by demonstrating that the tests were not sufficiently reliable to permit a conclusion that the product is superior." *Castrol*, 977 F.2d at 63. On the other hand, where a superiority claim makes no mention of tests or studies, a plaintiff must produce evidence affirmatively showing the claim to be false—*i.e.*, that the defendant's product is equal or inferior. *Id.* Likewise, where an advertisement does not make a superiority claim, a plaintiff must affirmatively prove the challenged statement to be false. *See, e.g.*, *Chesebrough-Pond's*, 747 F.2d at 119. Indeed, the plaintiff must do more than show that the statement is "unsubstantiated by acceptable tests or other proof." *Id.*

Here, none of the sales representatives' statements regarding somnolence involve claims of test-proven superiority. *Compare* Pl. Supp. 56.1 ¶¶ 36-45, 49-52, *with Chesebrough-Pond's*, 747 F.2d at 116, *Castrol, Inc.*, 977 F.2d at 59, *and McNeil-P.C.C., Inc.*, 938 F.2d at 1546. At most, the statements suggest that, due to pharmacokinetic differences between the products,

Zanaflex capsules cause less somnolence than Zanaflex tablets when taken with food. The statements do not, by contrast, "explicitly or implicitly represent[] that tests or studies prove" that there is less somnolence with Zanaflex capsules. *Castrol*, 977 F.2d at 63.[1] Accordingly, for the statements to give rise to liability under the Lanham Act, Plaintiffs must affirmatively prove them to be false.

Plaintiffs point to "a post-hoc analysis" of data from a single study "not designed or powered to detect differences in adverse events" (the "101 study"), which found no statistically significant difference between Zanaflex capsules and tablets with respect to adverse events such as somnolence. *See, e.g.*, Pl. Supp. 56.1 ¶¶ 60-67; Def. Supp. 56.1 ¶¶ 60-67. Based on this evidence, the Court concludes that no reasonable juror could find that Plaintiffs have affirmatively demonstrated that the sales representatives' statements were false. Plaintiffs' evidence merely shows the challenged statements to be "unsubstantiated by acceptable tests or other proof." *Chesebrough-Pond's*, 747 F.2d at 119. Plaintiffs cannot prove falsity by such evidence alone. *Id.* Therefore, to the extent that Plaintiffs' Lanham Act claim is based on Defendant's sales representatives' statements about somnolence, the claim cannot survive a motion for summary judgment.

[1] The Court acknowledges that some of the challenged statements refer to a graph of pharmacokinetic differences between Zanaflex capsules and tablets, *see, e.g.*, Pl. Supp. 56.1 ¶ 38 ("I asked [the doctor] about the most common complaint with Zanaflex tablets and he said the drowsiness and then we went to the graph and I discussed the capsules . . . ."), but concludes that these statements do not constitute claims of test-proven superiority. Presumably, the graph cited by the sales representatives is the same one featured on the FDA label, Def. Mem. App. A at 1, and in Defendant's promotional materials, *see, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74, which shows mean tizanidine plasma concentration curves over time. Plaintiffs do not argue otherwise. Likewise, Plaintiffs do not suggest that Defendant's sales representatives told doctors that the graph shows levels of somnolence. At most, the evidence indicates that the sales representatives encouraged doctors to draw an inference not directly supported by the graph—which is insufficient to trigger the "less stringent standard," *Glaxo Warner-Lambert*, 935 F. Supp. at 329, for proving falsity.

3. Reduced Cmax – Promotional Materials

Turning to Defendant's promotional materials, Plaintiffs contend that these materials contain false and misleading information concerning Cmax. First, Plaintiffs argue that the promotional materials falsely state that taking Zanaflex tablets with food increases Cmax by 30%, whereas taking Zanaflex capsules with food decreases Cmax by 20%. Specifically, Plaintiffs assert that this information is false because: (1) "[t]he 101 study . . . reports the true Cmax increase is 22.6%"; and (2) the FDA label states that Cmax is increased by *approximately* 30% when Zanaflex tablets are administered with food. Pl. Mem. 18-19. The Court disagrees. As an initial matter, there is no indication in any of Defendant's promotional materials that the Cmax percentages are based on the 101 study. Plaintiffs' conclusory assertion that Defendant derived the numerical information from this source does not establish a genuine dispute. *See, e.g.*, *Burt Rigid Box*, 302 F.3d at 91. Instead, it is clear that Defendant drew the information from the FDA label, which, again, states:

> When two 4 mg *tablets* are administered with food the mean maximal plasma concentration is increased by approximately 30% . . . . In contrast, when two 4 mg *capsules* are administered with food the mean maximal plasma concentration is decreased by 20% . . . . Consequently, the mean Cmax for the capsule when administered with food is approximately 2/3's the Cmax for the tablet when administered with food.

Def. Mem. App. A at 1 (emphasis added). Because the Cmax numbers are consistent with the FDA label, they cannot provide the basis for a Lanham Act false advertising claim. *See, e.g.*, *Mylan Pharm.*, 443 F. Supp. 2d at 460; *Cytyc Corp.*, 12 F. Supp. 2d at 301. Furthermore, the omission of the word "approximately" before the 30% figure does not render the promotional claim false. The Cmax information included in Defendant's promotional materials is "similar enough to the [FDA-]approved statements for the Court to conclude, as a matter of law, that [it is] neither false nor misleading." *Cytyc Corp.*, 12 F. Supp. 2d at 301 (noting that promotional

statements need not "correspond precisely to statements that the FDA has approved" for the court to find that they are non-actionable under the Lanham Act).

Plaintiffs also argue that the presentation of the 20% and 30% Cmax figures alongside a graph of mean tizanidine plasma concentration curves over time, *see, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74, is false and misleading. Pl. Mem. 19. The Court finds that a reasonable juror could determine that the juxtaposition of this text and image communicates a literally false message. The pharmacokinetic curves on the graph show mean plasma tizanidine concentration (*i.e.*, the mean concentration of tizanidine in the blood), which is distinct from Cmax. Pl. Supp. 56.1 ¶¶ 69-70; Def. Supp. 56.1 ¶¶ 69-70; *see also* Miller Decl. Ex. 17 ("Jusko Report") ¶ 43, ECF No. 97-8. The parties agree that Cmax is "the highest level of tizanidine in the blood at whatever time that occurs." Pl. Supp. 56.1 ¶ 70; Def. Supp. 56.1 ¶ 70. According to Plaintiffs, because "each subject exhibits his or her own Cmax at different times following administration of the dosage form, and not necessarily at the time point showing the highest mean concentration for all subjects combined," Jusko Report ¶ 43, "one cannot simply look at the highest point on each curve and say that that is Cmax," Pl. Supp. 56.1 ¶ 71. Defendant's promotional materials indicate that the highest points on the "Tablets with Food" and "Capsules with Food" curves represent a "30% Increase for Tablets" and "20% Decrease for Capsules," respectively. *See, e.g.*, *id.* ¶ 74; Def. Supp. 56.1 ¶ 74. The unambiguous message of this graphic is that mean tizanidine plasma concentration increases by 30% when Zanaflex tablets are taken with food and decreases by 20% when Zanaflex capsules are taken with food. Plaintiffs have also submitted evidence that "[i]f one were to calculate the difference between the highest points on each of the four pharmacokinetic curves, there is only a 13% increase in [mean tizanidine plasma concentration] for the tablets and only a 12% decrease in [mean tizanidine plasma concentration]

for the capsules." Pl. Supp. 56.1 ¶ 81. In addition, Defendant acknowledges that the graph "does not include" the 20% and 30% Cmax figures. Def. Supp. 56.1 ¶ 69. Based on this evidence, a reasonable juror could find that the challenged graphic is literally false.

To prevail on a Lanham Act false advertising claim, however, a plaintiff must do more than prove falsity. The plaintiff must also show materiality, which requires evidence that "the alleged inaccuracy in the statements at issue would influence the purchasing decisions of consumers." *Mylan Pharm.*, 443 F. Supp. 2d at 462; *see also, e.g.*, *Medisim Ltd. v. BestMed LLC*, 910 F. Supp. 2d 591, 618 (S.D.N.Y. 2012) ("Even were [the defendant's] statement literally false, [the plaintiff] would still need evidence that it was *material*, *i.e.* that it was likely to influence purchasing decisions."). Here, Plaintiffs have offered no evidence that misstating the extent to which food affects mean tizanidine plasma concentration was likely to influence consumers' purchasing decisions. At most, Plaintiffs have submitted evidence indicating that Defendant overstated the increase in mean tizanidine plasma concentration for Zanaflex tablets by 17% and overstated the decrease in mean tizanidine plasma concentration for Zanaflex capsules by 8%. Such evidence does not reveal anything about the impact on consumers' purchasing decisions. Accordingly, because Plaintiffs have failed to make a sufficient showing of materiality, the Court finds that their claim regarding the mean tizanidine plasma concentration graph cannot survive a motion for summary judgment.

4. Reduced Somnolence – Promotional Materials

Plaintiffs identify a "gatefold brochure" for Zanaflex capsules as another example of Defendant's allegedly false advertising. *See* Pl. Supp. 56.1 ¶¶ 83-84, Def. Supp. 56.1 ¶¶ 83-84. Specifically, Plaintiffs assert that this brochure—with its tagline "Flexible Control in a Capsule," images of the sun and moon, the words "day" and "night," and information about "Important

Pharmacokinetic Differences"—"convey[s] to doctors that taking Zanaflex [c]apsules with food will lead to a reduction in Cmax and somnolence." Pl. Mem. 22.[2] Thus, according to Plaintiffs, "a trier of fact could readily conclude that this gatefold message is literally false and misleading." *Id.* The Court disagrees. Again, "only an *unambiguous* message can be literally false." *Time Warner Cable*, 497 F.3d at 158. "[I]f the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." *Id.* Plaintiffs suggest that the brochure's only message is that administering Zanaflex capsules with food reduces somnolence. *See* Pl. Mem. 22. The Court finds that no reasonable juror could reach the same conclusion. Indeed, it is apparent that the brochure could be reasonably interpreted in a number of alternative ways (*e.g.*, Zanaflex capsules relieve symptoms throughout the entire day, Zanaflex capsules release the drug in a controlled manner, Zanaflex capsules allow for more effective treatment of spasticity over time). Therefore, Plaintiffs cannot prove the gatefold brochure to be literally false.

The Court likewise concludes that no reasonable juror could find that Plaintiffs have "show[n] that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." *Time Warner Cable*, 497 F.3d at 153. To meet this burden, a plaintiff "must demonstrate, by extrinsic evidence, that the challenged [advertisement] tend[s] to mislead or confuse consumers." *Tiffany (NJ) Inc.*, 600 F.3d at 112-12 (internal quotation marks and citation omitted). The plaintiff must produce such extrinsic evidence "even at the summary judgment stage." *Gameologist Grp.*, 838 F. Supp. 2d at 165. Here, Plaintiffs have provided no extrinsic evidence of consumer confusion. Therefore, with respect to the alleged falsity of the

[2] Because the Court has already determined that Defendant's promotional claims about Cmax cannot give rise to liability under the Lanham Act, *see supra* Sections II.B.1, 3, the Court will not address Cmax again in this section.

gatefold brochure, Plaintiffs have failed to make a showing sufficient to survive a motion for summary judgment.

5. Pharmacokinetic Differences – Promotional Materials

Finally, Plaintiffs take issue with various statements in Defendant's promotional materials regarding pharmacokinetic differences between Zanaflex capsules and tablets. Specifically, Plaintiffs note that Defendant's promotional materials: (1) "state unequivocally that 'Effects and Adverse Events *are* Dose Related to Plasma Levels of Tizanidine,'" whereas the FDA label "say[s] only that effects *may* be dose-related to plasma levels"; (2) assert that "[s]ignificant pharmacokinetic changes including plasma level differences *occur* when administering Zanaflex [c]apsules[] or tablets with food," whereas the FDA label "say[s] only that pharmacokinetic differences *may* result in clinically significant differences"; and (3) "declare that 'Important Pharmacokinetic Differences Exist Between Zanaflex Capsules . . . and Tablets,'" whereas the FDA label "nowhere reflects the qualitative judgment that any differences between Zanaflex [c]apsules and tablets are 'important.'" Pl. Mem. 25-26.

A promotional claim is not literally false simply because it exaggerates an FDA-approved statement. Indeed, a plaintiff alleging falsity bears a greater burden—that is, the plaintiff must affirmatively prove that the promotional claim is false. *See, e.g.*, *Chesebrough-Pond's*, 747 F.2d at 119. Plaintiffs have presented no evidence that would support a reasonable juror's conclusion that: (1) effects and adverse events are *not* dose related to plasma levels of tizanidine; (2) significant pharmacokinetic changes do *not* occur when administering Zanaflex capsules or tablets with food; and (3) *no* important pharmacokinetic differences exist between Zanaflex capsules and tablets. Likewise, to the extent that Plaintiffs suggest that these statements are misleading, they have provided no extrinsic evidence of consumer confusion. Moreover, even if

Plaintiffs had offered such evidence, no reasonable juror could find for Plaintiffs because they have produced no evidence that the alleged inaccuracies were likely to influence consumers' purchasing decisions. *See, e.g.*, *Medisim Ltd.*, 910 F. Supp. 2d at 618. Accordingly, Plaintiffs' Lanham Act claim fails.

CONCLUSION

For the reasons stated above, Defendant's motion for summary judgment is GRANTED.[3] The Clerk of Court is directed to terminate the motion at ECF No. 85 and to close the case.

SO ORDERED.

Dated: October 23, 2014
New York, New York

ANALISA TORRES
United States District Judge

[3] Because Plaintiffs' failure to make a sufficient showing on essential elements of their case entitles Defendant to judgment as a matter of law, the Court need not address Defendant's arguments regarding Plaintiffs' claim for damages. *See* Def. Mem. 21-25.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

APOTEX INC. and APOTEX CORP. ,

Plaintiffs,

11 **CIVIL** 8803 (AT)

-against-

JUDGMENT

ACORDA THERAPEUTICS, INC.,

Defendant.

----------X

Defendant having moved for summary judgment pursuant to Fed. R. Civ. P. 56, and the matter having come before the Honorable Analisa Torres, United States District Judge, and the Court, on October 23, 2014, having rendered its Memorandum and Order granting Defendant's motion for summary judgment, and directing the Clerk of Court to close the case, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Memorandum and Order dated October 23, 2014, Defendant's motion for summary judgment is granted; accordingly, the case is closed.

Dated: New York, New York
October 24, 2014

RUBY J. KRAJICK

Clerk of Court

BY:

Deputy Clerk

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